

Este documento foi elaborado com o objetivo de identificar as principais atualizações encontradas no documento "**European Union herbal monographs: Overview of recommendations for the uses of herbal medicinal products in the paediatric population**" publicado pela Agência Europeia de Medicamentos (EMA) em Março de 2023 e disponível através do link: <https://bit.ly/3Mrt9mE>

Para informações detalhadas sugerimos a consulta específica às monografias dos medicamentos fitoterápicos publicadas pela EMA e disponíveis no site do COMITEE ON HERBAL Medicinal Products (CHMP). Clique para acessar ao site: <https://bit.ly/3EexVPO>

Well-established use herbal medicinal products

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|--|--|--------------------------------|--|
| Agni casti fructus Monograph Assessment report | Urinary tract and genital disorders | For the treatment of premenstrual syndrome. | Herbal preparation Dry extract (DER 6-12:1), extraction solvent: ethanol 60% m/m | Herbal preparation in solid dosage form for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data.  |
| Aloes folii succus siccatus Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparation Dry extract (DER 1-3:1), extraction solvent: water, standardised to contain 28.6 -36.6% hydroxyanthracene derivatives, calculated as aloin (photometric method) | Standardised herbal preparations in liquid or solid dosage forms for oral use. | Adolescents Adults | The use is contraindicated. |
| Capsici fructus Monograph Assessment report | Pain and inflammation | For the relief of muscle pain such as low back pain. | Herbal preparations -Soft extract (DER 4-7:1), standardised to 2.0–2.78% total capsaicinoids, extraction solvent ethanol 80% (V/V) -Soft extract (DER 1.5–2.5:1), extraction solvent ethanol 96% (V/V) -Soft extract (DER 11-30:1), extraction solvent propan-2-ol | Herbal preparation in a medicated plaster or in semi-solid dosage forms for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| Cimicifugae rhizoma Monograph Assessment report | Urinary tract and genital disorders | For the relief of menopausal complaints such as hot flushes and profuse sweating. | Herbal preparations a) Dry extract (DER 5-10:1), extraction solvent ethanol 58% (V/V) b) Dry extract (DER 4.5-8.5:1), extraction solvent ethanol 60% (V/V) c) Dry extract (DER 6-11:1), extraction solvent propan-2-ol 40% (V/V) | Herbal preparation in solid dosage forms for oral use. | Female adults in the menopause | The indication is not relevant to children and adolescents. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------|---|--|---|---|---|
| Echinaceae purpureae herba Monograph Assessment report | Cough and cold | For the short-term prevention and treatment of common cold. | Herbal preparations - expressed juice (1.5-2.5:1) - dried juice corresponding to the expressed juice above | Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Frangulae cortex Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparations Comminuted herbal substance or herbal preparations thereof, standardized  | Standardised comminuted herbal substance as herbal tea for oral use. Standardised herbal preparations in liquid or solid dosage forms for oral use.  | Adolescents Adults Elderly | Children under 12 years of age: the use is contraindicated.  |
| Ginkgo folium Monograph Assessment report | Circulatory disorders | For the improvement of (age-associated) cognitive impairment and of quality of life in mild dementia. | Herbal preparation Dry extract (DER 35-67:1), extraction solvent: acetone 60% m/m3 | Herbal preparations in solid or liquid dosage forms for oral use. | Adults | The indication is not relevant to children and adolescents. |
| Hederae helicis folium Monograph Assessment report | Cough and cold | Used as an expectorant in case of productive cough. | Herbal preparations a) Dry extract (DER 4-8:1), extraction solvent ethanol 24-30% m/m b) Dry extract (DER 6-7:1), extraction solvent ethanol 40% m/m c) Dry extract (DER 3-6:1), extraction solvent ethanol 60% m/m d) Liquid extract (DER 1:1), extraction solvent ethanol 70% V/V e) Soft extract (DER 2.2-2.9:1), extraction solvent ethanol 50% V/V: propylene glycol (98:2) | Herbal preparations in solid or liquid dosage forms for oral use. | Children older than 2 years Adolescents Adults Elderly | Children under 2 years of age: the use is contraindicated.  |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|--|--|--|--|---|--|
| Hippocastani semen Monograph Assessment report    | Circulatory disorders  | For treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in | Herbal preparations Dry extracts (extraction solvent ethanol 40-80% (V/V) standardised to contain 6.5-10% triterpene glycosides, calculated as protoaeccigenin)  | Herbal preparations in modified or immediate release dosage forms for oral use.  | Adults Elderly   | The use is not recommended due to a lack of data on safety and efficacy. |
| Hyperici herba Monograph Assessment report | Mental stress and mood disorders | For the treatment of mild to moderate depressive episodes. | Herbal preparations a) Dry extract (DER 3-7:1), extraction solvent methanol (80% (V/V)) b) Dry extract (DER 3-6:1), extraction solvent ethanol (80% (V/V)) | Herbal preparation in solid dosage forms for oral use. | Adults Elderly   | The use is not recommended since no sufficient data are available. |
| Hyperici herba Monograph Assessment report | Mental stress and mood disorders | For the short-term treatment of symptoms in mild depressive disorders. | Herbal preparation c) Dry extract (DER 2.5-8:1), extraction solvent ethanol (50-68% (V/V)) | Herbal preparation in solid dosage forms for oral use. | Adults Elderly   | The use is not recommended since no sufficient data are available. |
| Lini semen Monograph Assessment report | Constipation | For the treatment of habitual constipation or in conditions in which easy defaecation with soft stool is desirable. | Herbal substance As defined in the Ph. Eur. Monograph | Herbal substance for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

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|--|-----------------------------|--|--|---|---|---|---|--|---|
| Menthae piperitae aetheroleum Monograph Assessment report | Gastro intestinal disorders | For the symptomatic relief of minor spasms of the gastrointestinal tract, flatulence and abdominal pain, especially in patients with irritable bowel syndrome. | Herbal preparation Essential oil | Herbal preparation in solid gastro-resistant dosage forms for oral use. |  New! | Children older than 8 years Adolescents Adults Elderly |  New! | The use is not recommended due to lack of data on safety and efficacy. |  New! |
|--|-----------------------------|--|--|---|---|---|---|--|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|--|--|---|--|---|
| Menthae piperitae aetheroleum Monograph Assessment report   | Pain and inflammation | For the symptomatic relief of mild tension type headache. | Herbal preparation Essential oil  | Herbal preparation in liquid or semi-solid dosage forms for cutaneous use.  | Adults Elderly  | The use is not recommended due to lack of data on safety and efficacy.  |
| Plantaginis ovatae semen Monograph Assessment report | Constipation | For the treatment of habitual constipation. | Herbal substance Dried ripe seeds Herbal preparation Powdered herbal substance | Solid dosage forms such as granules or powders for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Plantaginis ovatae semen Monograph Assessment report | Constipation | In conditions in which easy defaecation with soft stools is desirable, e.g. in cases of painful defaecation after rectal or anal surgery, anal fissures or haemorrhoids. | Herbal substance Dried ripe seeds Herbal preparation Powdered herbal substance | In solid dosage forms such as granules or powders for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Plantaginis ovatae seminis tegumentum Monograph Assessment report | Constipation | For the treatment of habitual constipation. | Herbal substance Episperm and collapsed adjacent layers removed from the seeds Herbal preparation Powdered herbal substance | Solid dosage forms such as granules or powders for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|--|--|---|--|--|
| Plantaginis ovatae semenis tegumentum Monograph Assessment report | Constipation | In conditions in which easy defaecation with soft stool is desirable, e.g. in cases of painful defaecation after rectal or anal surgery, anal fissures and haemorrhoids. | Herbal substance Episperm and collapsed adjacent layers removed from the seeds Herbal preparation Powdered herbal substance | In solid dosage forms such as granules or powders for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Plantaginis ovatae semenis tegumentum Monograph Assessment report | Constipation | In patients to whom an increased daily fibre intake may be advisable e.g. as an adjuvant in constipation predominant irritable bowel syndrome, as an adjuvant to diet in hypercholesterolemia. | Herbal substance Episperm and collapsed adjacent layers removed from the seeds Herbal preparation Powdered herbal substance | Solid dosage forms such as granules or powders for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Psyllii semen Monograph Assessment report | Constipation | For the treatment of habitual constipation. | Herbal substance Ripe, whole, dry seeds Herbal preparation Powdered herbal substance | In solid dosage forms such as granules or powders for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data |
| Psyllii semen Monograph Assessment report | Constipation | In conditions in which easy defaecation with soft stool is desirable, e.g. in cases of painful defaecation after rectal or anal surgery, anal fissures or haemorrhoids. | Herbal substance Ripe, whole, dry seeds Herbal preparation Powdered herbal substance | Solid dosage forms such as granules or powders for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------|--|--|--|----------------------------------|--|
| Rhamni purshianae cortex Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparations Comminuted herbal substance, or herbal preparations thereof, standardized  | Standardised comminuted herbal substance as herbal tea for oral use. Standardised comminuted herbal substance or herbal preparations in solid or liquid dosage forms for oral use.  | Adolescents Adults Elderly | Children under 12 years of age: the use is contraindicated.  |
| Rhei radix Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparation Comminuted herbal substance, or herbal preparations thereof, standardised.  | Standardised comminuted herbal substance as herbal tea for oral use. Standardised herbal preparations in liquid or solid dosage forms for oral use.  | Adolescents Adults Elderly | Children under 12 years of age: the use is contraindicated.  |
| Ricini oleum Monograph Assessment report | Constipation | Laxative for short term use in cases of occasional constipation. | Herbal preparation Fatty oil obtained from seeds of Ricinus communis L. by cold expression | Liquid or solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data |

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|---|-----------------------|--|---|---|--------|--|
| Salicis cortex <u>Monograph</u> <u>Assessment report</u> | Pain and inflammation | For the short-term treatment of low back pain. | Herbal preparation Dry extract (8-14:1) extraction solvent ethanol 70% (V/V), 15% total salicin | Quantified herbal preparation in solid dosage form. | Adults | The use is contraindicated due to the risk of Reye's syndrome. |
|---|-----------------------|--|---|---|--------|--|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---|--|--|--|--|--|
| Sennae folium Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparation Comminuted herbal substance or herbal preparations thereof, standardized  | Standardised comminuted herbal substance as herbal tea for oral use. Standardised herbal preparations in liquid or solid dosage forms for oral use.  | Adolescents Adults Elderly   | Children under 12 years of age: the use is contraindicated.  |
| Sennae fructus Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparation Comminuted herbal substance or herbal preparations thereof, standardized  | Standardised comminuted herbal substance as herbal tea for oral use. Standardised herbal preparations in liquid or solid dosage forms for oral use.  | Adolescents Adults Elderly   | Children under 12 years of age: the use is contraindicated.  |
| Sennae fructus Monograph Assessment report | Constipation  | For bowel cleansing prior to clinical procedures requiring bowel preparation.  | Herbal preparation Comminuted herbal substance or herbal preparations thereof, standardized  | Standardised comminuted herbal substance as herbal tea for oral use. Standardised herbal preparations in liquid or solid dosage forms for oral use.  | Adolescents Adults Elderly   | Children under 12 years of age: the use is contraindicated.  |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|---|--|---|----------------------------------|---|
| Thymi herba and Primulae radix Monograph Assessment report | Cough and cold | Used as an expectorant in case of productive cough. | <p>Herbal preparation</p> <p>a) Liquid extract from Thyme (DER 1:2-2.5), extraction solvent ammonia solution 10% m/m: glycerol 85% m/m: ethanol 90% V/V: water (1:20:70:109) and tincture from Primula root (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 50% V/V</p> <p>b) Liquid extract from Thyme (DER 1:2-2.5), extraction solvent ammonia solution 10% m/m: glycerol 85% m/m: ethanol 90% V/V: water (1:20:70:109) and liquid extract from Primula root (DER 1:2-2.5), extraction solvent ethanol 70% m/m</p> <p>c) Dry extract from Thyme (DER 6-10:1), extraction solvent ethanol 70% V/V and dry extract from Primula root (DER 6-7:1), extraction solvent ethanol 47.4% V/V</p> | Herbal preparations in liquid or solid dosage forms for oral use. | Adults | The use is not recommended due to lack of efficacy data |
| Valerianae radix Monograph Assessment report | Mental stress and mood disorders | Relief of mild nervous tension. | <p>Herbal preparations</p> <p>Dry extract (DER 3-7.s4:1), extraction solvent: ethanol 40-70% (V/V)</p> | Solid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Valerianae radix Monograph Assessment report | Sleep disorders and temporary insomnia | Sleep disorders. | <p>Herbal preparations</p> <p>Dry extract (DER 3-7.s4:1), extraction solvent: ethanol 40-70% (V/V)</p> | Solid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Valerianae radix and Lupuli flos Monograph Assessment report | Sleep disorders and temporary insomnia | For the relief of sleep disorders. | <p>Herbal preparations used in fixed combinations of</p> <p>a) Dry extracts of valerian root (DER 4-8:1, methanol 45-51% m/m) and hop strobile (DER 3-10:1, methanol 40-51% m/m)</p> <p>b) Dry extracts of valerian root (DER 4-7:1, ethanol 70% (V/V)) and hop strobile (DER 4-8:1, methanol 40% (V/V))</p> | Solid dosage forms for oral use. | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data.  |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-----------------------------|--|--|---|--------------------------|---|
| Vitis viniferae folium Monograph Assessment report | Circulatory disorders | For treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves. | Herbal preparation Dry extract (DER 4-6:1); extraction solvent water | Herbal preparation in solid dosage forms for oral use. | Adults | The indication is not relevant to children and adolescents. |
| Zingiberis rhizoma Monograph Assessment report | Gastro-intestinal disorders | For the prevention of nausea and vomiting in motion sickness. | Herbal preparation Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

Traditional use herbal medicinal products

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|--|---|--------------------------|---|
| Absinthii herba Monograph Assessment report | Loss of appetite | For temporary loss of appetite. | Herbal preparations - Comminuted herbal substance - Expressed juice from the fresh herb (1:0.5-0.9) - Tincture (1:5, ethanol 70% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use | Adults | The use is not recommended due to lack of adequate data. |
| Absinthii herba Monograph Assessment report | Gastro-intestinal disorders | For mild dyspeptic/gastrointestinal disorders. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Expressed juice from the fresh herb (1:0.5-0.9) - Tincture (1:5, ethanol 70% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use | Adults | The use is not recommended due to lack of adequate data. |
| Agni casti fructus Monograph Assessment report | Urinary tract and genital disorders | For the relief of minor symptoms in the days before menstruation (premenstrual syndrome). | Herbal preparations a) Powdered herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 68-70% (V/V) c) Dry extract (DER 7-13:1), extraction solvent ethanol 60% m/m. d) Dry extract (DER 10.0-18.5:1), extraction solvent ethanol 50-52% m/m e) | Herbal preparation in solid or liquid dosage forms for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data. |
| Agrimoniae herba Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild diarrhoea. | Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) c) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|---|---|---|---|
| Agrimoniae herba Monograph Assessment report | Mouth and throat disorders | For the symptomatic relief of minor inflammations of the mouth and throat. | Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) c) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Comminuted herbal substance for infusion preparation or decoction preparation for oromucosal use. Herbal preparations in liquid dosage forms for oral use or oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Agrimoniae herba Monograph Assessment report | Skin disorders & minor wounds | For the relief of minor skin inflammation and small, superficial wounds. | Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) c) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Comminuted herbal substance for infusion preparation or decoction preparation for cutaneous use or use as bath additive. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Agropyri repentis rhizoma Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 20-25% (V/V) c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 40% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. | Adolescents (preparation a) only Adults Elderly | The use is not recommended due to lack of adequate data.  |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|--|--|--|---|---|
| Althaeae radix Monograph Assessment report | Mouth and throat disorders | Used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. | Herbal preparations A- Comminuted herbal substance B- Liquid extract (DER1:19.5–23.5), extraction solvent water C- Macerate for preparation of syrup D- Dry extract (DER 3–9:1), extraction solvent water E- Liquid extract (DER 1:1), extraction solvent ethano 25% V/V | Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for macerate preparation for oromucosal use. Herbal preparations in liquid or solid dosage forms for oral or oromucosal use. | Preparations A,B,C,E: Children older than 3 years Adolescents Adults Preparation D: Children older than 6 years Adolescents Adults | The use is not recommended because medical advice should be sought. The use is not recommended because of solid dosage form (preparation d). |
| Althaeae radix Monograph Assessment report | Gastro-intestinal disorders | Used as a demulcent preparation for the symptomatic relief of mild gastrointestinal discomfort. | Herbal preparation A- Comminuted herbal substance E- Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage form for oral use | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Anisi aetheroleum Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild, spasmotic gastro-intestinal complaints including bloating and flatulence. | Herbal preparation Pimpinella anisum L., aetheroleum (anise oil) | Solid or liquid dosage forms for oral use. | Adults | The use is contraindicated due to lack of adequate data and the presence of estragole. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|--|--|--------------------------|--|
| Anisi aetheroleum Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal preparation Pimpinella anisum L., aetheroleum (anise oil) | Solid or liquid dosage forms for oral use. | Adults | The use is contraindicated due to lack of adequate data and the presence of estragole. |
| Anisi fructus Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. | Herbal substance Dried aniseed Herbal preparation Dried aniseed, comminuted or crushed | Herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Anisi fructus Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal substance Dried aniseed Herbal preparation Dried aniseed, comminuted or crushed | Herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Arctii radix Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. | Herbal preparations - Comminuted herbal substance as an infusion - Powdered herbal substance -Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Soft extract , extraction solvent water. - Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5) extraction solvent ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---------------------------------|--|--|--|---|--|
| Arctii radix Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations - Comminuted herbal substance as an infusion - Powdered herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Soft extract, extraction solvent water - Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5) extraction solvent ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Arctii radix Monograph Assessment report | Skin disorders and minor wounds | Used in treatment of seborrhoeic skin conditions. | Herbal preparations - Comminuted herbal substance as an infusion - Powdered herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Soft extract, extraction solvent water. - Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5) extraction solvent ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Arnicae flos Monograph Assessment report | Skin disorders and minor wounds | For the relief of bruises, sprains and localised muscular pain. | Herbal preparations - Tincture (DER 1:10), extraction solvent: ethanol 70% (v/v) - Tincture (DER 1:10), extraction solvent: ethanol 60% (v/v) - Tincture (DER 1:5), extraction solvent: ethanol 60% (v/v) - Liquid extract of fresh flowers (DER 1:20), extraction solvent: ethanol 50% (m/m) | Herbal preparations in semi-solid and liquid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Avenae fructus Monograph Assessment report | Skin disorders and minor wounds | For the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds. | Herbal preparation Dried fruits comminuted to oat flour 'Colloidal oatmeal' | Dried fruits comminuted to oat flour. 'Colloidal oatmeal' for cutaneous use. | Infants, Children, Adolescents, Adults | |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|---|--|---|--------------------------|---|
| Avenae herba Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress to aid sleep. | Herbal preparations - Comminuted herbal substance - Expressed juice from the fresh herb (1:0.64-0.80) - Liquid extract (1:4-6; ethanol 15-50% (V/V)) - Liquid extract (1:4-6; water) - Corresponding dry extracts | Solid or liquid dosage form or as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Avenae herba Monograph Assessment report | Sleep disorders and temporary insomnia | To aid sleep. | Herbal preparations - Comminuted herbal substance - Expressed juice from the fresh herb (1:0.64-0.80) - Liquid extract (1:4-6; ethanol 15-50% (V/V)) - Liquid extract (1:4-6; water) Corresponding dry extracts | Solid or liquid dosage form or as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Betulae folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 3-8:1), extraction solvent water d) Liquid extract prepared from fresh leaves (DER 1:2-2.4), extraction solvent water e) Liquid extract prepared from fresh leaves stabilised by 96% ethanol vapours (DER 1:1), extraction solvent ethanol 50- 60% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| Boldi folium Monograph Assessment report | Gastro-intestinal disorders | For symptomatic relief of dyspepsia and mild spasmotic disorders of the gastrointestinal tract. | Herbal preparations - Comminuted herbal substance - Dry extract (DER 5:1), extraction solvent water | Comminuted herbal substance as herbal tea for oral use. Herbal preparation in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data and because of concerns requiring medical advice. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|--|--|---|---|--|
| Bursae pastoris herba Monograph Assessment report | Urinary tract and genital disorders | For the reduction of heavy menstrual bleeding in women with regular menstrual cycles, after serious conditions have been excluded by a medical doctor. | Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Calendulae flos Monograph Assessment report | Skin disorders and minor wounds | For the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations a) Comminuted herbal substance b) Liquid extract (1:1), extraction solvent ethanol 40-50% (V/V) c) Liquid extract (1:1.8-2.2), extraction solvent ethanol 40-50% (V/V) d) Tincture (1:5), extraction solvent ethanol 70-90% (V/V) e) Liquid extract (1:10), extraction solvent fatty vegetable oil e.g. olive oil f) Extract (1:5-1:25), extraction solvent hardened vegetable fat, petroleum jelly  | Herbal substance or comminuted herbal substance for infusion for cutaneous use. Herbal preparations in liquid or semi-solid dosage forms for cutaneous use.  | Children older than 6 years Adolescents Adults Elderly | The use is not recommended due to lack of adequate data.  |
| Calendulae flos Monograph Assessment report | Mouth and throat disorders | For the symptomatic treatment of minor inflammations in the mouth or the throat. | Herbal substance As defined in the Ph. Eur. monograph Herbal ions a)  erbal substance d) extraction solvent ethanol 70-90% (V/V) e) | Herbal substance or comminuted herbal substance for infusion for oromucosal use. Herbal preparation in liquid dosage form for oromucosal use.  | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|--|--|--|---|--|
| Camelliae sinensis non fermentatum folium Monograph Assessment report | Fatigue and weakness | For relief of fatigue and sensation of weakness | Herbal substance Whole dried leaf Herbal preparations - Comminuted herbal substance - Powdered herbal substance | Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Carvi aetheroleum Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic relief of digestive disorders such as bloating and flatulence. | Herbal preparations Essential oil | Herbal preparation in liquid dosage forms for oral use. Herbal preparation in semi-solid dosage forms for cutaneous use. | Oral use: Adults Cutaneous use: Infants, Children, Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Carvi fructus Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic relief of digestive disorders such as bloating and flatulence. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations Comminuted herbal substance | Herbal substance or comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Caryophylii floris aetheroleum Monograph Assessment report | Mouth and throat disorders | For the symptomatic treatment of minor inflammations in the mouth or the throat. | Herbal preparation Essential oil obtained by steam distillation from the dried flower buds of Syzygium aromaticum (L.) Merill et L. M. Perry | Herbal preparations in liquid dosage forms for dental and oromucosal use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-----------------------------|---|--|--|--------------------------|--|
| Caryophylii floris aetheroleum Monograph Assessment report | Mouth and throat disorders | For the temporary relief of toothache due to a dental cavity. | Herbal preparation Essential oil obtained by steam distillation from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merill et L. M. Perry | Herbal preparations in liquid dosage forms for dental and oromucosal use. | Adults | The use is not recommended due to lack of adequate data. |
| Centaurii herba Monograph Assessment report | Gastro-intestinal disorders | Used in mild dyspeptic/gastrointestinal disorders. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (1:1; ethanol 25% (V/V)) - Tincture (1:5; ethanol 70% (V/V)) - Soft extract (1:10; water) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Centaurii herba Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (1:1; ethanol 25% (V/V)) - Tincture (1:5; ethanol 70% (V/V)) - Soft extract (1:10; water) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Chamomillae romanae flos Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 70% (V/V) | Herbal substance and comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---|---|---|--|----------------------------------|--|
| Cichorii intybi radix Monograph Assessment report | Gastro-intestinal disorders Loss of appetite | For the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence and slow digestion) and temporary loss of appetite. | Herbal preparations Comminuted herbal substance. | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |
| Cinnamomi corticis aetheroleum Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. | Herbal preparations Essential oil obtained by steam distillation from the cortex | Herbal preparation in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Cinnamomi cortex Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. | Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 70% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparation in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Cinnamomi cortex Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic treatment of mild diarrhoea. | Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 70% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) | Comminuted herbal substance as herbal tea for oral use Herbal preparation in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|---|--|--|--------------------------|--|
| Colae semen Monograph Assessment report | Fatigue and weakness | For symptoms of temporary fatigue and sensation of weakness. | Herbal preparations - Powdered herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 60% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 60% (V/V) | Powdered herbal substance in solid dosage forms for oral use. Powdered herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Crataegi folium cum flore Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor. | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 4-7:1), extraction solvent: methanol 70% V/V d) Dry extract (DER 4-7.1:1), extraction solvent: ethanol 45-70% V/V e) Liquid extract (DER 1:0.9-1.1), extraction solvent: ethanol 45% V/V f) Liquid extract (DER 1:2), extraction solvent: ethanol 45% V/V g) Liquid extract (DER 1:19.2-20), extraction solvent: sweet wine h) Expressed juice from the fresh leaves and flowers (DER 1:0.63-0.9) i) Expressed juice from the fresh leaves and flowers (DER 1:0.9-1.1) j) Tincture (DER 1:3.5-4.5), extraction solvent: ethanol 35% V/V | Comminuted herbal substance as herbal tea for oral use. Powdered herbal substance in solid dosage forms for oral use. Herbal preparations e) to j) in liquid dosage forms for oral use. Herbal preparations c), d) and k) in solid or liquid dosage forms for oral use. | Adults | The use is not recommended because of concerns requiring medical advice. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|--|---|---|--|--|
| <i>Crataegi folium cum flore</i> Monograph Assessment report | Sleep disorders | For relief of mild symptoms of mental stress and to aid sleep. | Herbal preparations a) Comminuted herbal substance k) Dry extract (DER 4-5:1), extraction solvent: water | Comminuted herbal substance as herbal tea for oral use. Herbal preparations k) in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| <i>Curcumae longae rhizoma</i> Monograph Assessment report | Gastro-intestinal disorders | Used for the relief of digestive disturbances, such as feelings of fullness, slow digestion and flatulence.  | Herbal preparations a) Powdered herbal substance b) Comminuted herbal substance c) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 70% (V/V) d) Dry extract (DER 13-25:1), extraction solvent ethanol 96% (V/V) e) Dry extract (DER 5.5-6.5:1), extraction solvent ethanol 50% (V/V) f) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Adults Elderly  | The use is not recommended due to lack of adequate data. |
| <i>Curcumae xanthorrhizae rhizoma</i> Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of digestive disturbances, such as feelings of fullness, slow digestion and flatulence. | Herbal preparations - Comminuted herbal substance - Dry extract (DER 20-50:1), extraction Solvent ethanol 96% (v/v) - Dry extract (DER 9-12:1), extraction solvent acetone | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---------------------------------|---|--|---|---|--|
| Cynarae folium Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic relief of digestive disorders such as dyspepsia with a sensation of fullness, bloating and flatulence. | Herbal preparations a) Comminuted dried leaves for herbal tea b) Powdered dried leaves c) Dry extract of dried leaves (DER 2.5-7.5:1), extraction solvent water d) Dry extract of fresh leaves (DER 15-35:1), extraction solvent water e) Soft extract of fresh leaves (DER 15-30:1), extraction solvent water f) Soft extract of dried leaves (DER 2.5-3.5:1), extraction solvent ethanol 20% (V/V)  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage form for oral use. | Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Echinaceae angustifoliae radix Monograph Assessment report | Cough and cold | For supportive treatment of common cold. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 45% (V/V) - Liquid extract (DER 1:1), extraction solvent: ethanol 45% (V/V) | Comminuted herbal substance as herbal tea for oral use. Solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Echinaceae pallidae radix Monograph Assessment report | Cough and cold | For the relief of symptoms of common cold.   | Herbal preparations a) Dry extract (DER 4-8:1), extraction solvent: ethanol 50% (V/V) b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 50% (V/V)  | Solid or liquid dosage forms for oral and oromucosal use.   | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |
| Echinaceae purpureae herba Monograph Assessment report | Skin disorders and minor wounds | For treatment of small superficial wounds. | Herbal preparation - Expressed juice - Dried expressed juice | Semi-solid or liquid dosage form for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|---|---|--------------------------|---|
| Echinaceae purpureae radix Monograph Assessment report | Cough and cold | For the relief of symptoms of common cold. | Herbal preparation - Dry extract (DER 5.5-7.5:1), extraction solvent ethanol 45% (V/V) | Solid dosage form for oral and oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Echinaceae purpureae radix Monograph Assessment report | Skin disorders and minor wounds | For the relief of spots and pimples due to mild acne | Herbal preparation - Dry extract (DER 4:1); extraction solvent water | Solid dosage form for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Eleutherococci radix Monograph Assessment report | Fatigue and weakness | For symptoms of asthenia such as fatigue and weakness. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (1:1, ethanol 30-40% (V/V)) - Dry extract (13-25:1, ethanol 28-40% (V/V)) - Dry extract (17-30:1, ethanol 70% (V/V)) - Dry aqueous extract (15-17:1) - Tincture (1:5, ethanol 40% (V/V)) - Liquid extract (1:11), extraction solvent sweet wine - Liquid extract (1:20), extraction solvent sweet wine | Comminuted herbal substance as herbal tea for oral use. Solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Epilobii herba Monograph Assessment report | Urinary tract and genital disorders | For the relief of lower urinary tract symptoms related to benign prostatic hyperplasia after serious conditions have been excluded by a medical doctor. | Herbal preparation - Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The indication is not relevant to children and adolescents. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|---|---|--------------------------|--|
| Equiseti herba Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations a) Comminuted herbal substance b) Expressed juice from fresh herbal substance (DER 1:1.6-2.0) c) Liquid extract from fresh herbal substance (DER 1:9), extraction solvent: water d) Dry extract (DER 4-7:1) extraction solvent: water e) Liquid extract (DER 1:5), extraction solvent: ethanol 96% (V/V) : water : sweet wine 16.5% (V/V) (16.5:13.5:70) (m/m) f) Liquid extract (DER 1:4.5-5.0) extraction solvent: sweet wine 16% (V/V):ethanol 96% (V/V) (91:9) (m/m) g) Liquid extract (DER 1:1) extraction solvent: 25% ethanol h)Liquid extract (DER 1:4-5), extraction solvent: ethanol 31.5% (V/V) i) Dry extract (DER 7.5-10.5:1) extraction solvent: ethanol 70% (V/V) | Comminuted herbal substance as herbal tea or in solid dosage forms for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Equiseti herba Monograph Assessment report | | For supportive treatment of superficial wounds. | Herbal preparations a) Comminuted herbal substance b) Expressed juice from fresh herbal substance (DER 1:1.6-2.0) | Comminuted herbal substance for infusion or decoction preparation for cutaneous use. Herbal preparations in liquid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Eschscholziae herba Monograph Assessment report | Mental stress & mood disorders | For relief of mild symptoms of mental stress | Herbal preparation Powdered herbal substance | Powdered herbal substance in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--------------------------------------|---|--|---|---|--|
| <i>Eschscholziae herba</i> Monograph Assessment report | Sleep disorders & temporary insomnia | Used to aid sleep. | Herbal preparation Powdered herbal substance | Powdered herbal substance in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| <i>Eucalypti aetheroleum</i> Monograph Assessment report | Cough and cold | For relief of cough associated with cold. | Herbal preparation Essential oil | Herbal preparation in solid or liquid dosage forms for oral use . Herbal preparations in liquid dosage forms for inhalation or as bath additives. Herbal preparations in liquid or semi-solid dosage forms for cutaneous use. | Oral use: Adolescents Adults. Cutaneous use; Inhalation; Use as bath additive: Children older than 4 years Adolescents Adults | Children younger than 30 months: the use is contraindicated because there is a risk that 1,8-cineole containing preparations, can induce laryngospasm. Children older than 30 months: the use is not recommended due to lack of adequate data.  |
| <i>Eucalypti aetheroleum</i> Monograph Assessment report | Pain and inflammation | For the symptomatic relief of localised muscle pain | Herbal preparation Essential oil | Herbal preparations in liquid dosage forms as bath additives. Herbal preparations in liquid or semi-solid dosage forms for cutaneous use. | Children older than 4 years Adolescents Adults | Children younger than 30 months: the use is contraindicated because there is a risk that 1,8-cineole containing preparations, can induce laryngospasm. Children older than 30 months: the use is not recommended due to lack of adequate data.  |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|--|--|--|--------------------------|--|
| Filipendulae ulmariae flos Monograph Assessment report  | Cough and cold | For the supportive treatment of common cold. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Filipendulae ulmariae flos Monograph Assessment report | Pain and inflammation | For the relief of minor articular pain. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Filipendulae ulmariae herba Monograph Assessment report | Cough and cold | For the supportive treatment of common cold. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) | Comminuted herbal substance as herbal tea for oral use. Powdered herbal substance in solid dosage forms for oral use. Herbal preparation in liquid dosage form for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|--|--|--|--|---|
| Filipendulae ulmariae herba Monograph Assessment report | Pain and inflammation | For the relief of minor articular pain. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) | Comminuted herbal substance as herbal tea for oral use. Powdered herbal substance in solid dosage forms for oral use. Herbal preparation in liquid dosage form for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Foeniculi amari fructus Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. | Herbal substance Dried fennel, bitter Herbal preparation Dried fennel, bitter, comminuted | Herbal tea for oral use. | Children older than 4 years Adolescents Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Foeniculi amari fructus Monograph Assessment report | Urinary tract and genital disorders | For symptomatic treatment of minor spasm associated with menstrual periods. | Herbal substance Dried fennel, bitter Herbal preparation Dried fennel, bitter, comminuted | Herbal tea for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Foeniculi amari fructus Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal substance Dried fennel, bitter Herbal preparation Dried fennel, bitter, comminuted | Herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|--|---|--|---|
| Foeniculi amari fructus aetheroleum Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal preparation <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i> , aetheroleum (Bitter fennel fruit, oil) | Solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Foeniculi dulcis fructus Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating, and flatulence. | Herbal substance Dried fennel, sweet Herbal preparation Dried fennel, sweet, comminuted | Solid dosage forms or as herbal tea for oral use. | Children older than 4 years Adolescents Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Foeniculi dulcis fructus Monograph Assessment report | Urinary tract and genital disorders | For symptomatic treatment of minor spasm associated with menstrual periods. | Herbal substance Dried fennel, sweet Herbal preparation Dried fennel, sweet, comminuted | Solid dosage forms or as herbal tea for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Foeniculi dulcis fructus Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal substance Dried fennel, sweet Herbal preparation Dried fennel, sweet, comminuted | Solid dosage forms or as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |

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| <p>Fragariae folium</p> <p>Monograph</p> <p>Assessment report</p> | <p>Urinary tract and genital disorders</p> <p>New!</p> <p>New!</p> | <p>Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</p> | <p>Herbal preparation</p> <p>Comminuted herbal substance</p> | <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>New!</p> | <p>Adolescents</p> <p>Adults</p> <p>Elderly</p> <p>New!</p> | <p>The use is not recommended due to lack of adequate data.</p> |
|--|--|--|---|---|--|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|---|---|---|--|--|--|
| Fragariae folium Monograph Assessment report  | Gastro-intestinal disorders   | For symptomatic treatment of mild diarrhoea. | Herbal preparation Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use.  | Adolescents Adults Elderly   | The use is not recommended due to lack of adequate data. |
| Fraxini folium Monograph Assessment report | Pain and inflammation | For relief of minor articular pain. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Fraxini folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Fucus vesiculosus thallus Monograph Assessment report | Gastro-intestinal disorders | Used as an adjuvant to reduced calorie diet to help weight loss in overweight adults. | Herbal preparations Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended because of concerns requiring medical advice. |

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|--|------------------------------------|---|---|---|---------------|---|
| <p>Fumariae herba</p> <p>Monograph</p> <p>Assessment report</p> | <p>Gastro-intestinal disorders</p> | <p>Used to increase bile flow for the relief of symptoms of indigestion (such as sensation of fullness, flatulence and slow digestion).</p> | <p>Herbal preparations</p> <ul style="list-style-type: none"> - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 3.5-5:1), extraction solvent water - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) - Juice of the fresh plant | <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in solid or liquid dosage forms for oral use.</p> | <p>Adults</p> | <p>The use is not recommended due to lack of adequate data.</p> |
|--|------------------------------------|---|---|---|---------------|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|--|---|---|--------------------------|---|
| Gentianae radix Monograph Assessment report | Gastro-intestinal disorders | Used in mild dyspeptic/gastrointestinal disorders. | Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 53% (V/V) c) Liquid extract (DER 1:1), extraction solvent ethanol 45% (V/V) d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V)  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use.  | Adults Elderly | The use is not recommended due to lack of adequate data.  |
| Gentianae radix Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 53% (V/V) c) Liquid extract (DER 1:1), extraction solvent ethanol 45% (V/V) d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V)  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use.  | Adults Elderly | The use is not recommended due to lack of adequate data. |
| Ginkgo folium Monograph Assessment report | Circulatory disorders | For the relief of heaviness of legs and the sensation of cold hands and feet associated with minor circulatory disorders, after serious conditions have been excluded by a medical doctor. | Herbal preparations Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---------------------------------|---|--|---|---|--|
| Ginseng radix Monograph Assessment report    | Fatigue and weakness | For symptoms of asthenia such as fatigue and weakness.  | Herbal preparations White ginseng: a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 2-7:1), extraction solvent ethanol 34-40% V/V d) Dry extract(DER 3-7:1),extraction solvent ethanol 40% V/V, containing 4% ginsenosides (sum of Rb1, Rb2, Rc, Rd,Re,Rf,Rg1, Rg2) e) Dry extract (DER 3-7:1), extraction solvent ethanol 57.9% V/V (=50% m/m)-60% V/V f) Dry extract (DER 3.3-5:1), extraction solvent methanol 60% V/V g) Soft extract (DER 1.7-3.2:1), extraction solvent ethanol 60%-70% V/V h) Soft extract (DER 2 -6:1), extraction solvent methanol 30% V/V i) Liquid extract (DER 1:0.8-1.2),extraction solvent ethanol 30.5% V/V (=25% m/m)-34% V/V j) Liquid extract (DER 1:11-13.6), extraction solvent liquor wine Red ginseng: a) Powdered herbal substance b) Dry extract (DER 2-4.5:1), extraction solvent ethanol 60% V/V  | Comminuted herbal substance (herbal preparation a) as herbal tea for oral use. Herbal preparations f, k, l in solid dosage forms for oral use. Herbal preparations g, h, i, j in liquid dosage forms for oral use. Herbal preparation b, c, d, e in solid and liquid dosage forms. | Adults Elderly   | The use is not recommended due to lack of adequate data. |
| Hamamelidis cortex Monograph Assessment report | Skin disorders and minor wounds | For relief of minor skin inflammation and dryness of the skin. | Herbal preparations - Dried comminuted herbal substance - Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Dry extract (DER 5-7.7:1), extraction solvent ethanol 30% m/m | Herbal preparations in semi-solid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---------------------------------|--|---|--|--|--|
| Hamamelidis cortex Monograph Assessment report | Circulatory disorders | For symptomatic relief of itching and burning associated with haemorrhoids. | Herbal preparations - Dried comminuted herbal substance - Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Dry extract (DER 5-7.7:1), extraction solvent ethanol 30% m/m | Comminuted herbal substance for decoction for anorectal use. Herbal preparations in semi-solid or liquid dosage forms for anorectal use. Herbal preparations in solid dosage forms for rectal use. | Adults | The use is not recommended due to lack of adequate data. |
| Hamamelidis cortex Monograph Assessment report | Mouth and throat disorders | Used as a mouthwash and gargles for relief of minor inflammation of mucous membranes of the oral cavity. | Herbal preparations - Dried comminuted herbal substance - Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Dry extract (DER 5-7.7:1), extraction solvent ethanol 30% m/m | Comminuted herbal substance for decoction for oromucosal use. Herbal preparations in liquid dosage forms for oromucosal use. | Adults | The use is not recommended due to lack of adequate data. |
| Hamamelidis folium Monograph Assessment report | Skin disorders and minor wounds | For relief of minor skin inflammation and dryness of the skin. | Herbal preparations - Distillate prepared from fresh leaves and bark (1:1.12-2.08; ethanol 6% m/m) - Distillate prepared from dried twigs (1:2; ethanol 14-15%) | Herbal preparations in semisolid or liquid dosage forms for cutaneous, use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |

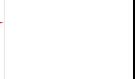
| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---------------------------------|--|--|---|--|--|
| <i>Hamamelidis folium</i> Monograph Assessment report | Circulatory disorders | For symptomatic relief of itching and burning associated with haemorrhoids. | Herbal preparations - Distillate prepared from fresh leaves and bark (1:1.12-2.08; ethanol 6% m/m) - Distillate prepared from dried twigs (1:2; ethanol 14-15%) | Herbal preparations in semisolid or liquid dosage forms for anorectal use. Herbal preparations in solid dosage forms for rectal use. | Adults | The use is not recommended due to lack of adequate data. |
| <i>Hamamelidis folium</i> Monograph Assessment report | Mouth and throat disorders | Used as a mouthwash and gargles for relief of minor inflammation of mucous membranes of the oral cavity. | Herbal preparations - Dried comminuted herbal substance - Tincture (fresh leaves) (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% (V/V) - Liquid extract (fresh leaves) (DER 1:1), extraction solvent ethanol 45% (V/V) - Liquid extract (DER 1:1), extraction solvent ethanol 30% m/m - Liquid extract (DER 1:2), extraction solvent ethanol 60% (V/V) | For decoction for oromucosal use. Herbal preparations in semisolid or liquid dosage forms for oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| <i>Hamamelidis folium et cortex aut ramunculus destillatum</i> Monograph Assessment report | Skin disorders and minor wounds | For relief of minor skin inflammation and dryness of the skin. | Herbal preparations - Dried comminuted herbal substance - Tincture (fresh leaves) (Ratio of herbal substance to extraction solvent 1:10, extraction solvent ethanol 45% (V/V) - Liquid extract (fresh leaves) (DER 1:1), extraction solvent ethanol 45% (V/V) - Liquid extract (DER 1:1), extraction solvent ethanol 30% m/m - Liquid extract (DER 1:2), extraction solvent ethanol 60% (V/V) | Herbal preparations in semisolid or liquid dosage forms for cutaneous use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|---|--|--|--------------------------|--|
| Hamamelidis folium et cortex aut ramunculus destillatum Monograph Assessment report | Eye discomfort | Used for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun. | Herbal preparations - Dried comminuted herbal substance - Tincture (fresh leaves) (Ratio of herbal substance to extraction solvent 1:10, extraction solvent ethanol 45% (V/V) - Liquid extract (fresh leaves) (DER 1:1), extraction solvent ethanol 45% (V/V) - Liquid extract (DER 1:1), extraction solvent ethanol 30% m/m - Liquid extract (DER 1:2), extraction solvent ethanol 60% (V/V) | Liquid dosage forms for ocular use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Harpagophyt radix Monograph Assessment report | Pain and inflammation | For relief of minor articular pain. | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V d) Soft extract (DER 2.5-4.0:1), extraction solvent ethanol 70% V/V e) Dry extract (DER 1.5-2.5:1), extraction solvent water f) Dry extract (DER 5-10:1), extraction solvent water g) Dry extract (DER 2.6-4:1), extraction solvent ethanol 30% V/V h) Dry extract (DER 1.5-2.1:1), extraction solvent ethanol 40% V/V i) Dry extract (DER 3-5:1), extraction solvent ethanol 60% V/V j) Dry extract (DER 3-6:1), extraction solvent ethanol 80% V/V k) Dry extract (DER 6-12:1), extraction solvent ethanol 90% V/V l) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate experience. |
| Harpagophyt radix Monograph Assessment report | Gastro-intestinal disorders | For the relief of mild digestive disorders such as bloating and flatulence and where there is loss of appetite. | Herbal preparations a) Comminuted herbal substance d) Soft extract (DER 2.5-4.0:1), extraction solvent ethanol 70% V/V e) Dry extract (DER 1.5-2.5:1), extraction solvent water g) Dry extract (DER 2.6-4:1), extraction solvent ethanol 30% V/V i) Dry extract (DER 3-5:1), extraction solvent ethanol 60% V/V | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate experience. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|--|--|--|---|--------------------------------------|---|
| Helichrysi flos Monograph Assessment report New! | Gastro-intestinal disorders | Used in digestive disorders with a feeling of fullness and bloating. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Herniariae herba Monograph Assessment report New! | Urinary tract and genital disorders New! | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. New! | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults Elderly New! | The use is not recommended due to lack of adequate data. New! |
| Hippocastani cortex Monograph Assessment report | Circulatory disorders | For relief of symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. | Herbal preparations Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Hippocastani cortex Monograph Assessment report | Circulatory disorders | For symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor. | Herbal preparations Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------|--|--|--|--------------------------|--|
| Hippocastani semen Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. | <p>Herbal preparations</p> <ul style="list-style-type: none"> a) Dry extract corresponding to a specified amount of triterpene glycosides, calculated as protoescigenin, extraction solvent ethanol 25-50% (V/V) b) Liquid extract (DER 1:3.5-5), extraction solvent ethanol 50% (V/V) c) Dry extract (DER 5-10:1), extraction solvent methanol 80% (V/V) d) Dry extract (DER 5-8:1), extraction solvent methanol 80% (V/V) e) Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 50% (V/V) f) Dry extract (DER 5-7:1), extraction solvent ethanol 60% (V/V) g) Liquid extract (DER 1:1.5-2.5), extraction solvent ethanol 55% V/V h) Liquid extract (DER 1:2), extraction solvent ethanol 19% m/m i) Dry extract (DER 3-6:1), extraction solvent water  | Herbal preparations in semi-solid dosage forms for cutaneous use. Herbal preparations in solid or liquid dosage forms for oral use.    | Adults Elderly | The use is not recommended because of concerns requiring medical advice. |

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|---|-----------------------|---|--|--|----------------------------------|---|
| Hippocastani semen Monograph Assessment report | Circulatory disorders | For relief of signs of bruises, such as local oedema and haematoma. | Herbal preparations | Herbal preparations in semi-solid dosage forms for cutaneous use. Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults Elderly | The use is not recommended in the absence of sufficient safety data.   |
| | | | a) Dry extract corresponding to a specified amount of triterpene glycosides, calculated as protoescigenin, extraction solvent ethanol 25-50% (V/V) b) Liquid extract (DER 1:3.5-5), extraction solvent ethanol 50% ethanol (V/V) c) Dry extract (DER 5-10:1), extraction solvent methanol 80% (V/V) d) Dry extract (DER 5-8:1), extraction solvent methanol 80% (V/V) e) Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 50% (V/V) f) Dry extract (DER 5-7:1), extraction solvent ethanol 60% (V/V) g) Liquid extract (DER 1:1.5-2.5), extraction solvent ethanol 55% V/V h) Liquid extract (DER 1:2), extraction solvent ethanol 19% m/m i) Dry extract (DER 3-6:1), extraction solvent water | | | |
| | | | j) | | | |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|---|--|--|--|--|--|
| Hyperici herba Monograph Assessment report | Mental stress and mood disorders | For the relief of temporary mental exhaustion. | Herbal preparations a) Dry extract (DER 4:7:1), extraction solvent ethanol 38% (m/m) = 45% V/V c) Liquid extract (DER 1:13), extraction solvent maize oil or other suitable vegetable oil d) Tincture (ratio herbal substance: extraction solvent 1:5), extraction solvent ethanol 50-70% (V/V) e) Tincture (ratio herbal substance: extraction solvent 1:10), extraction solvent ethanol 45-50% (V/V) f) Liquid extract (DER 1:2-7), extraction solvent ethanol 50% (V/V) g) Liquid extract from fresh herb (DER 1:1), extraction solvent ethanol 96% (V/V) h) Expressed juice from the fresh herb (DER 1:0.5-0.9) j) Comminuted herbal substance k) Powdered herbal substance  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations a), k) in solid dosage forms for oral use. Herbal preparations c), d), e), f), g), h) in liquid dosage forms for oral use. | Adults Elderly   | The use is not recommended since no sufficient data are available. |
| Hyperici herba Monograph Assessment report  | Mental stress and mood disorders   | For the supportive treatment of nervous restlessness and associated with difficulties in falling asleep.  | Herbal preparations Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use.  | Adults Elderly   | The use is not recommended since no sufficient data are available. |

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|--|--|--|--|--|---|
| <p>Hyperici herba</p> <p>Monograph</p> <p>Assessment report</p> | <p>Skin disorders and minor wounds</p> <p>For the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds.</p> | <p>Herbal preparations</p> <p>b) Liquid extract (DER 1:4-20), extraction solvent vegetable oil d) Tincture (ratio herbal substance: extraction solvent 1:5), extraction solvent ethanol 50-70% (V/V) e) Tincture (ratio herbal substance: extraction solvent 1:10), extraction solvent ethanol 45-50% (V/V)) Comminuted herbal substance</p> <p>New!</p> | <p>Comminuted herbal substance for infusion preparation for cutaneous use.</p> <p>Herbal preparations in liquid or semi-solid dosage forms for cutaneous use.</p> <p>New!</p> | <p>Adolescents Adults Elderly</p> <p>New!</p> | <p>The use is not recommended since no data on the safe use in children are available.</p> <p>New!</p> |
|--|--|--|--|--|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|--|---|--|---|
| <i>Hyperici herba</i> Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic relief of mild gastrointestinal discomfort. | Herbal preparations i) Stabilised expressed juice from fresh herb: the fresh herb is first stabilised over a boiling ethanol, then pressed and adjusted with water to a DER of 1:1. j) Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use. Herbal preparation in liquid dosage forms for oral use.  | Adults Elderly  | The use is not recommended since no sufficient data are available.  |
| <i>Juglandis folium</i> Monograph Assessment report | Skin disorders and minor wounds | For the relief of minor inflammatory conditions of the skin. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance for decoction preparation for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| <i>Juglandis folium</i> Monograph Assessment report | Skin disorders and minor wounds | Used in excessive perspiration of hands and feet. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance for decoction preparation for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| <i>Juniperi aetheroleum</i> Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. | Herbal preparations Essential oil obtained by steam distillation from the ripe, non-fermented berry cones | Herbal preparation in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

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|---|-----------------------------|---|---|---|--------|--|
| Juniperi aetheroleum Monograph Assessment report | Gastro-intestinal disorders | For symptomatic relief of digestive disorders such as dyspepsia and flatulence. | Herbal preparations Essential oil obtained by steam distillation from the ripe, non-fermented berry cones | Herbal preparation in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
|---|-----------------------------|---|---|---|--------|--|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|---|--|--------------------------|--|
| <i>Juniperi aetheroleum</i> Monograph Assessment report | Pain and inflammation | Used as adjuvant in the relief of minor muscular and articular pain. | Herbal preparations Essential oil obtained by steam distillation from the ripe, non-fermented berry cones | Herbal preparation in liquid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| <i>Juniperi galbulus</i> Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. | Herbal substance Cone berries Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1) with 25% ethanol (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) - Soft extract (DER 1.7-1.8:1), extraction solvent water | Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal substance or herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| <i>Juniperi galbulus</i> Monograph Assessment report | Gastro-intestinal disorders | For symptomatic relief of digestive disorders such as dyspepsia and flatulence | Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1) with 25% ethanol (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) | Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal substance or herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| <i>Lavandulae aetheroleum</i> Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress and exhaustion and to aid sleep. | Herbal preparations Essential oil obtained by steam distillation from the flowering tops of <i>Lavandula angustifolia</i> Miller | Herbal preparation in liquid dosage form for oral use and as a bath additive. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|---|---|--|--------------------------|--|
| Lavandulae aetheroleum Monograph Assessment report | Sleep disorders and temporary insomnia | For relief of mild symptoms of mental stress and exhaustion and to aid sleep. | Herbal preparations Essential oil obtained by steam distillation from the flowering tops of <i>Lavandula angustifolia</i> Miller | Herbal preparation in liquid dosage form for oral use and as a bath additive. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Lavandulae flos Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress and exhaustion and to aid sleep. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations - Comminuted herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 50-60% (V/V) | Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage form for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Lavandulae flos Monograph Assessment report | Sleep disorders and temporary insomnia | For relief of mild symptoms of mental stress and exhaustion and to aid sleep. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations - Comminuted herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 50-60% (V/V) | Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage form for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Lecithinum ex soya Monograph Assessment report | Fatigue and weakness | For the relief of temporary fatigue and sensation of weakness. | Herbal preparations Soya-bean lecithin (de-oiled phospholipids from soya bean) | Liquid or solid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|----------------------------------|---|--|---|--------------------------|--|
| Leonuri cardiacae herba Monograph Assessment report | Mental stress and mood disorders | Used to relieve symptoms of nervous tension. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Tinctures and liquid extract in liquid dosage forms for oral use. Powdered herbal substance for oral use. Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Leonuri cardiacae herba Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Tinctures and liquid extract in liquid dosage forms for oral use. Powdered herbal substance for oral use. Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|----------------------------------|--|--|--|---|---|
| Lichen islandicus Monograph Assessment report | Mouth and throat disorders | Used as a demulcent for the symptomatic treatment of oral or pharyngeal irritation | Herbal preparations a) Comminuted herbal substance b) Soft extract (DER 2-4:1), extraction solvent water c) Soft extract (DER 0.4-0.8:1), extraction solvent water d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 40% V/V | Comminuted herbal substance as herbal tea for oral use (a). Herbal preparations in liquid form for oral use (d). Herbal preparations in solid dosage forms for oromucosal use (b,c). | Preparation a): Adolescents Adults Preparation d): Adults Preparations b),c): Children older than 6 years Adolescents Adults | a, d: The use is not recommended due to lack of adequate data. b, c: The use is not recommended because of the pharmaceutical form(solid dosage form). |
| Lichen islandicus Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Lini semen Monograph Assessment report | Gastro-intestinal disorders | For use as a demulcent preparation for the symptomatic relief of mild gastrointestinal discomfort. | Herbal substance As defined in the Ph. Eur. monograph | Herbal substance for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| Lupuli flos Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress. | Herbal preparations - Comminuted herbal substance - Powered herbal substance - Liquid extract (1:1) extraction solvent ethanol/water 45% (V/V) - Liquid extract (1:10) extraction solvent sweet wine - Tincture (1:5) extraction solvent ethanol 60% (V/V) - Dry extract (4-5:1) extraction solvent methanol 50 % V/V | Comminuted herbal substance as herbal tea for oral use. Solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|--|--|--|---|----------------------------------|--|
| Lupuli flos Monograph Assessment report  | Sleep disorders and temporary insomnia | Used to aid sleep. | Herbal preparations - Comminuted herbal substance - Powered herbal substance - Liquid extract (1:1) extraction solvent ethanol/water 45% (V/V) - Liquid extract (1:10) extraction solvent sweet wine - Tincture (1:5) extraction solvent ethanol 60% (V/V) - Dry extract (4-5:1) extraction solvent methanol 50 % V/V | Comminuted herbal substance as herbal tea for oral use. Solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Malvae folium Monograph Assessment report    | Cough and cold | Used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance for infusion or decoction preparation for oromucosal use.  | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |
| Malvae folium Monograph Assessment report     | Gastro-intestinal disorders | Used as a demulcent preparation for the symptomatic relief of mild gastrointestinal discomfort. | Herbal preparations Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for infusion or decoction preparation for oral use.  | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |

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|--|--|--|--|---|--|--|
| Malvae sylvestris flos Monograph Assessment report  | Cough and cold   | Used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. | Herbal preparations Comminuted herbal substance  | Comminuted herbal substance for infusion or decoction preparation for oromucosal use  | Adolescents Adults Elderly   | The use is not recommended due to lack of adequate data. |
|--|--|--|--|---|--|--|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|---|---|---|--|--|---|
| Malvae sylvestris flos Monograph Assessment report  | Gastro-intestinal disorders   | Used as a demulcent preparation for the symptomatic relief of mild gastrointestinal discomfort. | Herbal preparations Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for infusion or decoction preparation for oral use  | Adolescents Adults Elderly   | The use is not recommended due to lack of adequate data.  |
| Marrubii herba Monograph Assessment report  | Cough and cold   | Used as an expectorant in cough associated with cold. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Expressed juice (DER 1:0.70-0.90) - Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 20-30% V/V  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use.  | Adolescents Adults   | The use is not recommended due to lack of adequate data.  |
| Marrubii herba Monograph Assessment report | Gastro-intestinal disorders | Used for symptomatic treatment of mild dyspeptic complaints such as bloating and flatulence. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Expressed juice (DER 1:0.70-0.90) - Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 20-30% V/V | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|--|--|--|--|
| Marrubii herba Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Expressed juice (DER 1:0.70-0.90) - Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 20-30% V/V | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Mate folium Monograph Assessment report | Fatigue and weakness | For symptoms of fatigue and sensation of weakness. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Mate folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Matricariae flos Monograph Assessment report | Gastrointestinal disorders | For the symptomatic treatment of minor gastro-intestinal complaints such as bloating and minor spasms. | Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 96% V/V: water : ammonia solution 10% m/m (50:47.5:2.5) d) Liquid extract (DER 1:1), extraction solvent ethanol 48% V/V: ammonia solution 10% m/m (39:1) ³ e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V: ammonia solution 10% m/m (14.7:1) g) Liquid extract (DER 1:1.7-2.6), extraction solvent ethanol 48% V/V i) Liquid extract (DER 1:2), extraction solvent ethanol 70% V/V j) Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3) k) Liquid extract (DER 1:1.8-2.1), extraction solvent ethanol 52% V/V : macrogol hydroxystearate (99.5:0.5) l) Liquid extract (DER 1:4.0-4.5) extraction solvent ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. | Preparation a Infants from 6 months Children Adolescents Adults Preparations e,g,k,l Children older than 6 years Adolescents Adults Preparations b,d,i,j Adolescents Adults | The use is not recommended due to lack of adequate data. |

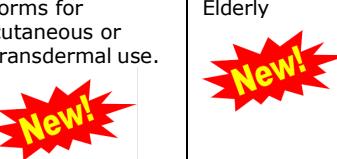
| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|----------------------------|--|--|---|--|--|
| Matricariae flos Monograph Assessment report | Cough and cold | For the relief of symptoms of common cold. | Herbal preparations a) Comminuted herbal substance d) Liquid extract (DER 1:1), extraction solvent ethanol 48% V/V: ammonia solution 10% m/m (39:1) e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V: ammonia solution 10% m/m (14.7:1) g) Liquid extract (DER 1:1.7-2.6), extraction solvent ethanol 48% V/V h) Liquid extract (DER 1:1), extraction solvent ethanol 55% V/V j) Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3) k) Liquid extract (DER 1:1.8-2.1), extraction solvent ethanol 52% V/V : macrogol hydroxystearate (99.5:0.5) l) Liquid extract (DER 1:4.0-4.5) extraction solvent ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) | Herbal substance or comminuted herbal substance as herbal tea for oral use and inhalation. Herbal preparations in liquid dosage forms for preparation of dilutions for steam inhalation. | Preparation h: Children older than 6 years Adolescents Adults Preparations a,d,e,g,j,k,l: Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Matricariae flos Monograph Assessment report | Mouth and throat disorders | For the treatment of minor ulcers and inflammations of the mouth and throat. | Herbal preparations a) Comminuted herbal substance c) Liquid Extract (DER 1:4.3-5.7), extraction solvent ethanol 96% V/V : water : ammonia solution 10% m/m (50:47.5:2.5) d) Liquid extract (DER 1:1), extraction solvent ethanol 48% V/V: ammonia solution 10% m/m (39:1) e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V: ammonia solution 10% m/m (14.7:1) h) Liquid extract (DER 1:1), extraction solvent ethanol 55% V/V i) Liquid extract (DER 1:2), extraction solvent ethanol 70% V/V j) Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3) k) Liquid extract (DER 1:1.8-2.1), extraction solvent ethanol 52% V/V : macrogol hydroxystearate (99.5:0.5) l) Liquid extract (DER 1:4.0-4.5) extraction solvent ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) | Herbal substance or comminuted herbal substance for infusion preparation for oromucosal use. Herbal preparations in liquid dosage forms for preparation of dilutions for oromucosal use. | Preparations a, h: Children older than 6 years Adolescents Adults Preparations c,d,e,i,j,k,l: Adolescents Adults | The use is not recommended due to lack of adequate data. |

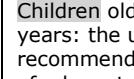
| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------|--|--|--|---|--|
| Matricariae flos Monograph Assessment report | Skin disorders & minor wounds | For adjuvant therapy of irritations of skin and mucosae in the anal and genital region, after serious conditions have been excluded by a medical doctor. | Herbal preparations a) Comminuted herbal substance d) Liquid extract (DER 1:1), extraction solvent ethanol 48% V/V: ammonia solution 10% m/m (39:1) e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V: ammonia solution 10% m/m (14.7:1) g) Liquid extract (DER 1:1.7-2.6), extraction solvent ethanol 48% V/V h) Liquid extract (DER 1:1), extraction solvent ethanol 55% V/V j) Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3) k) Liquid extract (DER 1:1.8-2.1), extraction solvent ethanol 52% V/V : macrogol hydroxystearate (99.5:0.5) l) Liquid extract (DER 1:4.0-4.5) extraction solvent ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) m) Liquid extract (DER 2.7-5.5:1), extraction solvent ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) n) Dry extract (DER 11-16:1), extraction solvent ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) o) Liquid extract (DER 1:2.0-2.8), extraction solvent propan-2-ol 48% V/V | Herbal preparations in semi-solid dosage forms for cutaneous use. Herbal preparations in liquid dosage forms for use as bath additives. | Preparations m,o: Infants from 4 weeks Children Adolescents Adults Preparations a,d,e,g,h,j,k,l,n : Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------|--|--|--|--|--|
| Matricariae flos Monograph Assessment report | Skin disorders & minor wounds | For the treatment of minor inflammation of the skin (sunburn) and superficial wounds and small boils (furuncles). | Herbal preparations a) Commинuted herbal substance c) Liquid Extract (DER 1:4.3-5.7), extraction solvent ethanol 96% V/V : water : ammonia solution 10% m/m (50:47.5:2.5) ³ d) Liquid extract (DER 1:1), extraction solvent ethanol 48% V/V: ammonia solution 10% m/m (39:1) ³ e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V: ammonia solution 10% m/m (14.7:1) f) Dry extract (DER 4-7:1), extraction solvent ethanol 50% m/m g) Liquid extract (DER 1:1.7-2.6), extraction solvent ethanol 48% V/V i) Liquid extract (DER 1:2), extraction solvent ethanol 70% V/V j) Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3) k) Liquid extract (DER 1:1.8-2.1), extraction solvent ethanol 52% V/V : macrogol hydroxystearate (99.5:0.5) l) Liquid extract (DER 1:4.0-4.5) extraction solvent ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) m) Liquid extract (DER 2.7-5.5:1), extraction solvent ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) n) Dry extract (DER 11-16:1), extraction solvent ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) o) Liquid extract (DER 1:2.0-2.8), extraction solvent propan-2-ol 48% V/V | Herbal preparations in semi-solid dosage forms for cutaneous use. Herbal preparations in liquid dosage forms for use as bath additives. | Preparations m,o: Infants from 4 weeks Children Adolescents Adults Preparations a,c,d,e,f,g,i,j,k,l,n: Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Matricariae aetheroleum Monograph Assessment report | Skin disorders & minor wounds | For adjuvant therapy of irritations of skin and mucosae in the anal and genital region, after serious conditions have been excluded by a medical doctor. | Herbal preparation Essential oil | Herbal preparations in liquid dosage forms for use as a bath additive. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------|---|--|---|--------------------------|--|
| Melaleucae alternifoliae aetheroleum Monograph Assessment report | Skin disorders & minor wounds | For treatment of small superficial wounds and insect bites. | Herbal preparation Essential oil | Herbal preparation in liquid and semi-solid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Melaleucae alternifoliae aetheroleum Monograph Assessment report | Skin disorders & minor wounds | For treatment of small boils (furuncles and mild acne). | Herbal preparation Essential oil | Herbal preparation in liquid and semi-solid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Melaleucae alternifoliae aetheroleum Monograph Assessment report | Skin disorders & minor wounds | For the relief of itching and irritation in cases of mild athlete's foot. | Herbal preparation Essential oil | Herbal preparation in liquid and semi-solid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Melaleucae alternifoliae aetheroleum Monograph Assessment report | Mouth and throat disorders | For symptomatic treatment of minor inflammation of the oral mucosa | Herbal preparation Essential oil | Herbal preparation in liquid dosage form for oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|--|--|---|---|--------------------------|--|
| Meliloti herba Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. | Herbal preparation - Comminuted herbal substance - Powdered herbal substance | Comminuted herbal substance as herbal tea, infusion, for oral use. Herbal substance in solid dosage forms for oral use | Adults | The indication is not relevant to children and adolescents. |
| Meliloti herba Monograph Assessment report | Pain and inflammation | For the treatment of minor inflammations of the skin. | Herbal preparation Liquid extract, ratio of herbal substance to extraction solvent 1:3, extraction solvents: ethanol 70% (V/V), rapeseed oil | Semi-solid dosage forms for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| Melissae folium Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 45-53% V/V - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45-53 % V/V - Dried water or ethanol (45-53% V/V) extracts corresponding to the tea, liquid extract and tincture above | Herbal substance or herbal preparations in solid or liquid dosage forms for oral use or as herbal tea. | Adolescents Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Melissae folium Monograph Assessment report | Sleep disorders and temporary insomnia | Used to aid sleep. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 45-53% V/V - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45-53 % V/V - Dried water or ethanol (45-53% V/V) extracts corresponding to the tea, liquid extract and tincture above | Herbal substance or herbal preparations in solid or liquid dosage forms for oral use or as herbal tea. | Adolescents Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|---------------------------------|--|---|--|---|---|
| Melissae folium Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild gastrointestinal complaints including bloating and flatulence. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 45-53% V/V - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45-53 % V/V - Dried water or ethanol (45-53% V/V) extracts corresponding to the tea, liquid extract and tincture above | Herbal substance or herbal preparations in solid or liquid dosage forms for oral use or as herbal tea. | Adolescents Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Menthae piperitae aetheroleum Monograph Assessment report | Pain and inflammation | For the symptomatic relief of localised muscle pain. | Herbal preparation Essential oil | Herbal preparation in liquid or semi-solid dosage forms for cutaneous or transdermal use. | Children older than 4 years Adolescents Adults Elderly | Children younger than 2 years: the use is contraindicated. Children between 2-4 years: the use is not recommended due to lack of adequate data.  |
| Menthae piperitae aetheroleum Monograph Assessment report | Skin disorders and minor wounds | For the symptomatic relief of localised pruritic conditions in intact skin. | Herbal preparation Essential oil | Herbal preparation in liquid or semi-solid dosage forms for cutaneous or transdermal use. | Children older than 4 years Adolescents Adults Elderly | Children younger than 2 years: the use is contraindicated. Children between 2-4 years: the use is not recommended due to lack of adequate data.  |
| Menthae piperitae aetheroleum Monograph Assessment report | Cough and cold | For the relief of symptoms in coughs and colds. | Herbal preparation Essential oil | Herbal preparation in liquid or semi-solid dosage forms for cutaneous or transdermal use. | Adolescents Adults Elderly | Children younger than 2 years: the use is contraindicated. Children older than 2-4 years: the use is not recommended due to lack of adequate data.   |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|---|--|--|---|---|
| Menthae piperitae aetheroleum Monograph Assessment report | Cough and cold | For the relief of symptoms in coughs and colds. | Herbal preparation Essential oil | Herbal preparation in liquid dosage forms for inhalation.   | Adolescents Adults Elderly | Children younger than 2 years: the use is contraindicated. Children older than 2 years: the use is not recommended due to lack of adequate data.   |
| Menthae piperitae aetheroleum Monograph Assessment report | Cough and cold | For the relief of symptoms in coughs and colds. | Herbal preparation Essential oil | Herbal preparation in liquid or solid dosage forms for oral and oromucosal use. | Adolescents Adults Elderly | Children younger than 2 years: the use is contraindicated. Children older than 2 years: the use is not recommended due to lack of adequate data. |
| Menthae piperitae folium Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic relief of digestive disorders such as dyspepsia and flatulence. | Herbal substance <i>Mentha x piperita L., folium</i> (dried peppermint leaf) Herbal preparations a) Comminuted herbal substance b) Tincture (1:5; ethanol 45% (V/V)) c) Tincture (1:5; ethanol 70% (V/V)) | Herbal substance and comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use.   | Children older than 4 years Adolescents Adults Elderly | Children younger than 4 years: the use is not recommended due to lack of adequate data.   |
| Menyanthidis trifoliatae folium Monograph Assessment report | Gastro-intestinal disorders | Used for the relief of mild digestive disorders such as bloating and flatulence. | Herbal preparations a) Comminuted herbal substance   | Comminuted herbal substance as herbal tea for oral use.   | Adults Elderly | The use is not recommended due to lack of adequate data.   |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|---|--|--|---|--|
| Menyanthidis trifoliatae folium Monograph Assessment report   | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use.  | Adults Elderly   | The use is not recommended due to lack of adequate data. |
| Menyanthidis trifoliatae folium Monograph Assessment report   | Pain and inflammation | Used for relief of minor articular and muscular pain, | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1) extraction solvent ethanol 25% (V/V) d) Tincture (1:5), extraction solvent 45% ethanol (V/V)  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use.  | Adults Elderly   | The use is not recommended due to lack of adequate data. |
| Millefolii flos Monograph Assessment report | Loss of appetite | For temporary loss of appetite. | Herbal substance Dried inflorescence Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:5.8), extraction solvent liquor vine: ethanol 96% (V/V) (91:9 m/m) | Herbal substance and comminuted herbal substance as herbal tea for oral use. Herbal preparation in liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|--|--|---|----------------------------------|---|
| Millefolii flos Monograph Assessment report | Gastro-intestinal disorders | Symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. | Herbal substance Dried inflorescence Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:5.8), extraction solvent liquor vine: ethanol 96% (V/V) (91:9 m/m) | Herbal substance and comminuted herbal substance as herbal tea for oral use. Herbal preparation in liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Millefolii flos Monograph Assessment report | Skin disorders and minor wounds | Treatment of small superficial wounds. | Herbal substance Dried inflorescence Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:5.8), extraction solvent liquor vine: ethanol 96% (V/V) (91:9 m/m) | Herbal substance for infusion preparation for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Millefolii flos Monograph Assessment report | Urinary tract and genital disorders | Symptomatic treatment of minor spasm associated with menstrual periods. | Herbal substance Dried inflorescence Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:5.8), extraction solvent liquor vine: ethanol 96% (V/V) (91:9 m/m) | Herbal substance and comminuted herbal substance as herbal tea for oral use. Herbal preparation in liquid dosage forms for oral use. | Adolescents Adults | Prepubertal children: the indication is not relevant to this age category. |
| Millefolii herba Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations a) Comminuted herbal substance b) Expressed juice from fresh herb (DER: 1:0.65-0.93) c) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 31.5% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use. | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data.  |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|---|---|----------------------------------|--|
| Millefolii herba Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.  | Herbal preparations a) Comminuted herbal substance b) Expressed juice from fresh herb (DER: 1:0.65-0.93) c) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 31.5% (V/V) f) Dry extract (DER 6-9:1), extraction solvent water  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use.  | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |
| Millefolii herba Monograph Assessment report | Skin disorders and minor wounds | For the treatment of small superficial wounds.  | Herbal preparations a) Comminuted herbal substance | Comminuted herbal substance for infusion preparation for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Millefolii herba Monograph Assessment report | Urinary tract and genital disorders | For the symptomatic treatment of minor spasm associated with menstrual periods.  | Herbal preparations a) Comminuted herbal substance g) Dry extract (DER 5-10:1), extraction solvent water  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms for oral use.  | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. |
| Myrrha Monograph Assessment report | Skin disorders and minor wounds | For treatment of minor wounds and small boils (furuncles). | Herbal preparation Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 90% V/V)) | Herbal preparation in liquid dosage forms for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-----------------------------|--|---|---|--------------------------|--|
| Myrrha Monograph Assessment report | Mouth and throat disorders | For treatment of minor ulcers and inflammation in the mouth (stomatitis and gingivitis). | Herbal preparation Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 90% (V/V) | Herbal preparation in liquid dosage forms for oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Myrtilli fructus recens Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. | Herbal preparation Dry extract; DER 153-76:1; extraction solvent methanol 70% v/v containing 36% anthocyanosides, corresponding to 25% anthocyanidins | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Myrtilli fructus recens Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of cutaneous capillary fragility. | Herbal preparation Dry extract; DER 153-76:1; extraction solvent methanol 70% v/v containing 36% anthocyanosides, corresponding to 25% anthocyanidins | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Myrtilli fructus siccus Monograph Assessment report | Gastrointestinal disorders | For symptomatic treatment of mild diarrhoea. | Herbal substance Ripe, dry fruits Herbal preparation Comminuted herbal substance | Herbal substance or comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Myrtilli fructus siccus Monograph Assessment report | Mouth and throats disorders | For symptomatic treatment of minor inflammations of the oral mucosa. | Herbal substance Ripe, dry fruits Herbal preparation Comminuted herbal substance | Herbal substance or comminuted herbal substance as herbal tea for decoction preparation for oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|--|--|---|--|
| Oenotherae oleum Monograph Assessment report | Skin disorders and minor wounds | For the symptomatic relief of itching in acute and chronic dry skin conditions exclusively based upon long-standing use.  | Herbal preparations Fatty oil obtained from seeds of <i>Oenothera biennis</i> L. or <i>Oenothera lamarckiana</i> L. by extraction and/or expression | Herbal preparation in solid dosage forms for oral use. | Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Oleae folium Monograph Assessment report | Urinary tract and genital disorders | Used to promote the renal elimination of water, in mild cases of water retention after serious conditions have been excluded by a medical doctor. | Herbal substance Fresh or dried leaves Herbal preparations - Comminuted dried leaves - Powdered dried leaves in solid dosage forms for oral use. | Herbal substance or comminuted herbal substance as herbal tea for oral use. Powdered dried leaves in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Ononidis radix Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints | Herbal preparations Comminuted herbal substance. | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Origani dictamni herba Monograph Assessment report | Cough and cold | For the relief of cough associated with cold | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------|---|--|--|---|--|
| Origani dictamni herba Monograph Assessment report | Gastro-intestinal disorders | For the relief of mild gastrointestinal disorders | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Origani dictamni herba Monograph Assessment report | Skin disorders & minor wounds | For the relief of minor skin inflammations and bruises. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance for infusion or decoction preparation for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| Origani majorana herba Monograph Assessment report | Gastro-intestinal disorders | Used for the symptomatic relief of mild spasmodic gastro-intestinal complaints such as bloating and flatulence. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Origani majorana herba Monograph Assessment report | Skin disorders & minor wounds | Used for relief of irritated skin around the nostrils. | Herbal preparation Extract (ratio of herbal substance to extraction solvent 1:5), extraction solvents ethanol 96% V/V and white petroleum jelly. | Herbal preparations in semi-solid dosage forms for cutaneous use. | Children older than 1 year Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|---|---|--|--------------------------|--|
| Orthosiphonis folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 25% m/m d) Dry extract (DER 5-7:1), extraction solvent water e) Dry extract (DER 8-12:1), extraction solvent ethanol 60% (V/V)) f) Dry extract (DER 7-8:1), extraction solvent ethanol 70% (V/V)) g) Dry extract (DER 5-7:1), extraction solvent ethanol 30% (V/V))  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid or dosage forms for oral use.  | Adults Elderly | The use is not recommended due to lack of adequate data. |
| Passiflorae herba Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (1:8 ; extraction solvent 25% ethanol) - Liquid extract (1:8 ; extraction solvent 45% ethanol) - Liquid extract 1:3.6) extraction solvent ethanol 60%V/V - Liquid extract (1:1 ; extraction solvent 25% ethanol) -Liquid extract (1:1 ; extraction solvent 70% ethanol) - Liquid extract (1:3.8-4.3) extraction solvent ethanol (96% V/V) + glycerol (85% m/m) + Water (11.8 + 1 + 7.9) Dried extracts corresponding to the tea and liquid extracts above | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Passiflorae herba Monograph Assessment report | Sleep disorders and temporary insomnia | Used to aid sleep. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (1:8 ; extraction solvent 25% ethanol) - Liquid extract (1:8 ; extraction solvent 45% ethanol) - Liquid extract 1:3.6) extraction solvent ethanol 60%V/V - Liquid extract (1:1 ; extraction solvent 25% ethanol) - Liquid extract (1:1 ; extraction solvent 70% ethanol) - Liquid extract (1:3.8-4.3) extraction solvent ethanol (96% V/V) + glycerol (85% m/m) + Water (11.8 + 1 + 7.9) Dried extracts corresponding to the tea and liquid extracts above | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|--|--|--|--|
| Pelargonii radix Monograph Assessment report | Cough and cold | For the symptomatic treatment of common cold. | Herbal preparations a) Liquid extract (DER 1:8-10), extraction solvent ethanol 11% (m/m) b) Dry extract, (DER 4-25:1), extraction solvent ethanol 11% (m/m) | Herbal preparations in liquid and solid dosage forms for oral use. | Children older than 6 years Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Phaseoli fructus sine semine Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use | Adults | The use is not recommended due to lack of adequate data. |
| Pilosellae herba cum radice Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. | Herbal preparations: a) Comminuted herbal substance b) Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Pistacia Lentiscus, resin (mastix) | | Used in mild dyspeptic disorders. | Herbal preparation Powdered herbal substance | Powdered herbal substance in solid dosage form for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Pistacia Lentiscus, resin (mastix) | | Used for the symptomatic treatment of minor inflammations of the skin and as an aid in healing of minor wounds. | Herbal preparation Powdered herbal substance | Powdered herbal substance in semi-solid dosage form for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|---|---|---|--|
| <i>Plantaginis lanceolatae folium</i> Monograph Assessment report | Mouth and throat disorders | Used as a demulcent for the symptomatic treatment of oral or pharyngeal irritations and associated dry cough. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 3-6:1); extraction solvent: water - Liquid extract (DER 1: 0.8-1.2); extraction solvent: ethanol:20-40% V/V -Soft extract (DER 1.5-1.7:1); extraction solvent: ethanol 20% m/m - Expressed juice (DER 1:0.5-0.9) from the fresh herb - Syrup according to ÖAB 2009 (formally, the native herbal preparation is a liquid extract (DER 1:1); extraction solvent: water) -Dry extract (DER 3-5:1); extraction solvent: ethanol 20% m/m - Liquid extract (DER 1: 5.8-5.9); extraction solvent: water | Comminuted herbal substance as herbal tea for oral use. Powdered herbal substance in a solid dosage form and other herbal preparations in liquid or solid dosage forms for oral and/or oromucosal use. | Oral use: Children older than 3 years. Oromucosal use: Adults | Oral use: the use is not recommended due to lack of adequate data and because medical advice should be sought. Oraalmucosal use: the use is not recommended due to lack of adequate data. |
| <i>Polygoni aviculalis herba</i> Monograph Assessment report | Cough and cold | Used for the relief of symptoms of common cold. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| <i>Polygoni aviculalis herba</i> Monograph Assessment report | Mouth and throat disorders | Used for symptomatic treatment of minor inflammations in the mouth or the throat. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance for decoction preparation for oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| <i>Polygoni aviculalis herba</i> Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|---|--|---|--|---|
| Polypodii rhizoma Monograph Assessment report | Cough and cold | Used as an expectorant in cough and cold. | Herbal preparation Comminuted herbal substance for tea preparation | Solid dosage forms for oral use (tea preparation). | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Polypodii rhizoma Monograph Assessment report | Constipation | For short-term use in cases of occasional constipation. | Herbal preparation Comminuted herbal substance for tea preparation | Solid dosage forms for oral use (tea preparation). | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Primulae flos Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal substance Whole or cut, dried flowers Herbal preparations - Liquid extract (1:1, extraction solvent ethanol 25% (V/V)) - Comminuted herbal substance for tea preparation | Herbal substance or comminuted herbal substance for tea preparation or other herbal preparation in liquid and solid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Primulae radix Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal substance Whole or cut, dried rhizome and root Herbal preparations - Dry extract (3-9:1), extraction solvent ethanol 40-50% (V/V) - Liquid extract (1:1), extraction solvent ethanol 70% (V/V), - Liquid extract (1:2.0-2.5), extraction solvent ethanol 70% (V/V) - Tincture (1:5), extraction solvent ethanol 70% (V/V) - Soft extract (5-10:1), extraction solvent water - Soft extract (1-4:1), extraction solvent ethanol 20-55% (V/V) - Soft extract (6-10:1), extraction solvent methanol, water, ammonia solution 10% (50,0:49,5:0,5) - Soft extract (6-10:1), extraction solvent methanol 50% - Comminuted herbal substance for tea preparation | Herbal substance or comminuted herbal substance for tea preparation or other herbal preparations in liquid and solid dosage forms for oral use. | Children older than 4 years Adolescents Adults | The use is not recommended because medical advice should be sought. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|---|---|--------------------------|---|
| Pruni africanae cortex Monograph Assessment report | Urinary tract and genital disorders | For the relief of lower urinary tract symptoms related to benign prostatic hyperplasia after serious conditions have been excluded by a medical doctor. | Herbal preparations Soft extract (DER 114-222:1), extraction solvent chloroform; (stabilised by 1.2 % of ethanol >99.9 %) | Herbal preparations in solid dosage forms for oral use. | Adults | The indication is not relevant to children and adolescents. |
| Quercus cortex Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild diarrhoea. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 5.0-6.5:1), extraction solvent ethanol 50% m/m | Comminuted herbal substance as a herbal tea for oral use. Herbal preparation in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Quercus cortex Monograph Assessment report | Pain and inflammation | For symptomatic treatment of minor inflammation of the oral mucosa or skin. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as a herbal tea for a decoction preparation for oromucosal or cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| Quercus cortex Monograph Assessment report | Circulatory disorders | For symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as a herbal tea as a decoction preparation for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|---|--|--|--------------------------|--|
| Rhodiola roseae rhizoma et radix Monograph Assessment report | Mental stress and mood disorders | For temporary relief of symptoms of stress, such as fatigue and sensation of weakness. | Herbal preparation Dry extract (DER 1.5-5:1), extraction solvent ethanol 67-70% (V/V) | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Rhodiola roseae rhizoma et radix Monograph Assessment report | Sleep disorders and temporary insomnia | For temporary relief of symptoms of stress, such as fatigue and sensation of weakness. | Herbal preparation Dry extract (DER 1.5-5:1), extraction solvent ethanol 67-70% (V/V) | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Ribis nigri folium Monograph Assessment report | Pain and inflammation | For relief of minor articular pain. | Herbal preparations - Comminuted herbal substance - Dry extract (DER 7:1), extraction solvent water: dry extract 7:1, water) - Powdered herbal substance | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Ribis nigri folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparation - Dry extract (DER 7:1), extraction solvent water: dry extract (7:1, water) - Powdered herbal substance | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------|---|---|---|--------------------------|--|
| Rosae flos Monograph Assessment report | Mouth and throat disorders | Used for mild inflammations of the oral and pharyngeal mucosa. | Herbal substance Dried petals Herbal preparation Comminuted herbal substance | Herbal substance or comminuted herbal substance for infusion preparation for oromucosal use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Rosae flos Monograph Assessment report | Skin disorders & minor wounds | Used for relief of minor skin inflammation. | Herbal substance Dried petals Herbal preparation Comminuted herbal substance | Herbal substance or comminuted herbal substance for infusion preparation for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Rosmarini aetheroleum Monograph Assessment report | Gastro-intestinal disorders | For symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract. | Herbal preparation Essential oil | Herbal preparation in liquid or semi-solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Rosmarini aetheroleum Monograph Assessment report | Circulatory disorders | For relief of minor muscular and articular pain and in minor peripheral circulatory disorders. | Herbal preparation Essential oil | Herbal preparation in liquid or semi-solid dosage forms for cutaneous use and as a bath additive. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|--|--|--------------------------|---|
| Rosmarini folium Monograph Assessment report | Gastro-intestinal disorders | For symptomatic relief of dyspepsia and mild spasmotic disorders of the gastrointestinal tract. | Herbal substance Whole or fragmented, dried leaf Herbal preparations - Comminuted herbal substance - Extract (DER 1:17.5-18.9), extraction solvent: liqueur wine: - Extract (DER 1:12.5-13.5), extraction solvent: liqueur wine -Expressed juice (DER 1:1.8-2.2) from Rosmarini herba recens - Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V | Herbal substance and/or comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data and because medical advice should be sought. |
| Rosmarini folium Monograph Assessment report | Circulatory disorders | Used as an adjuvant in the relief of minor muscular and articular pain and in minor peripheral circulatory disorders. | Herbal substance Whole or fragmented, dried leaf Herbal preparation Comminuted herbal substance | Herbal substance and/or comminuted herbal substance use as bath additive. Herbal preparations in liquid dosage forms for use as bath additive. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Rubi idaei folium Monograph Assessment report | Urinary tract and genital disorders | For the symptomatic relief of minor spasm associated with menstrual periods. | Herbal preparations - Comminuted herbal substance - Dry extract (4:1): extraction solvent water | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage form for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|--|--|---|--------------------------|--|
| Rubi idaei folium Monograph Assessment report | Mouth and throat disorders | For the symptomatic treatment of mild inflammation in the mouth or throat. | Herbal preparations - Comminuted herbal substance - Dry extract (4:1): extraction solvent water | Comminuted herbal substance for infusion preparation for oromucosal use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data. |
| Rubi idaei folium Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic treatment of mild diarrhoea. | Herbal preparations - Comminuted herbal substance - Dry extract (4:1): extraction solvent water | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid dosage form for oral use. | Adults | Prepubertal children: the indication is not relevant to this age category. Pubertal children and adolescents: the use is not recommended due to lack of adequate data. |
| Rusci rhizoma Monograph Assessment report | Circulatory disorders | Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. | Herbal preparations a) Powdered herbal substance b) Dry extract (DER 2.5-6.5:1); extraction solvent water c) Dry extract (DER 5-8.5:1); extraction solvent ethanol 80% (V/V) d) Dry extract (DER 6-9:1); extraction solvent ethanol 96% (V/V) | Herbal substance or herbal preparation in solid dosage forms for oral use. | Adults | The indication is not relevant to children and adolescents. |
| Rusci rhizoma Monograph Assessment report | Circulatory disorders | For symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by a medical doctor. | Herbal preparations a) Powdered herbal substance b) Dry extract (DER 2.5-6.5:1); extraction solvent water c) Dry extract (DER 5-8.5:1); extraction solvent ethanol 80% (V/V) | Herbal substance or herbal preparation in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

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| <p>Sabalis serrulatae fructus</p> <p>Monograph</p> <p>Assessment report</p> | <p>Urinary tract and genital disorders</p> | <p>For the relief of lower urinary tract symptoms related to benign prostatic hyperplasia, after serious conditions have been excluded by a doctor.</p> | <p>Herbal preparation Soft extract (DER 7.5-14.3:1), extraction solvent: ethanol 90% to 96 % m/m</p> | <p>Herbal preparations in solid dosage form for oral use.</p> | <p>Adults</p> | <p>The use is not relevant because the indication does not occur in children and adolescents.</p> |
|--|--|---|---|---|---------------|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-----------------------------|---|--|--|--------------------------|--|
| Salicis cortex Monograph Assessment report | Pain and inflammation | Used for the relief of minor articular pain. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 8-20:1) extraction solvent water - Dry extract (DER 16-23:1) extraction solvent water - Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V - Tincture (1:5), extraction solvent ethanol 25% V/V | Solid or liquid dosage form, or as herbal tea for oral use. | Adults | The use is contraindicated due to the risk of Reye's syndrome. |
| Salicis cortex Monograph Assessment report | Pain and inflammation | Used for headache. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 8-20:1) extraction solvent water - Dry extract (DER 16-23:1) extraction solvent water - Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V - Tincture (1:5), extraction solvent ethanol 25% V/V | Solid or liquid dosage form, or as herbal tea for oral use. | Adults | The use is contraindicated due to the risk of Reye's syndrome. |
| Salicis cortex Monograph Assessment report | Cough and cold | Used for the relief of fever associated with common cold. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Dry extract (DER 8-20:1) extraction solvent water - Dry extract (DER 16-23:1) extraction solvent water - Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V - Tincture (1:5), extraction solvent ethanol 25% V/V | Solid or liquid dosage form, or as herbal tea for oral use. | Adults | The use is contraindicated due to the risk of Reye's syndrome. |
| Salviae officinalis folium Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild dyspeptic, complaints such as heartburn and bloating. | Herbal preparations - Comminuted herbal substance - Dry extract (DER 4-7:1), extraction solvent water - Liquid extract (DER 1:3.5-5), extraction solvent ethanol 31.5% V/V - Liquid extract (DER 1:4-6), extraction solvent liquor wine: ethanol 96% V/V (38.25:61.75 m/m) - Tincture (ratio of herbal substance to extraction solvent 1 | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|---------------------------------|--|---|--|--------------------------|--|
| Salviae officinalis folium Monograph Assessment report | Skin disorders and minor wounds | For relief of excessive sweating. | Herbal preparations - Comminuted herbal substance - Dry extract (DER 4:7:1), extraction solvent water - Liquid extract (DER 1:3.5-5), extraction solvent ethanol 31.5% V/V - Liquid extract (DER 1:4-5) extraction solvent ethanol 50% V/V | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Salviae officinalis folium Monograph Assessment report | Skin disorders and minor wounds | For relief of minor skin inflammations. | Herbal preparations - Comminuted herbal substance | Comminuted herbal substance for infusion preparation for cutaneous use. | Adults | The use is not recommended due to lack of adequate data. |
| Salviae officinalis folium Monograph Assessment report | Mouth and throat disorders | For the symptomatic treatment of inflammations in the mouth or the throat. | Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 70% V/V - Liquid extract (DER 1:3.5-5), extraction solvent ethanol 31.5% V/V - Liquid extract (DER 1:4-6), extraction solvent liquor wine: ethanol 96% V/V (38.25:61.75 m/m) - Tincture (ratio of herbal substance to extraction solvent 1 | Comminuted herbal substance for infusion preparation for oromucosal use. Herbal preparations in liquid or semi-solid dosage forms for oromucosal use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-----------------------------|--|---|--|---|--|
| Sambuci flos Monograph Assessment report | Cough and cold | Used for the relief of early symptoms of common cold.  | Herbal substance As defined in the Ph. Eur. monograph. Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) c) Tincture (DER 1:5), extraction solvent ethanol 25% (V/V)  | Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage forms for oral use.  | Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Sideritis herba Monograph Assessment report | Cough and cold | For the relief of cough associated with cold. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Sideritis herba Monograph Assessment report | Gastro-intestinal disorders | For the relief of mild gastrointestinal discomfort. | Herbal preparations Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |

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| <p>Silybi mariani fructus</p> <p>Monograph</p> <p>Assessment report</p> <p>New!</p> | <p>Gastro-intestinal disorders</p> <p>New!</p> | <p>For the symptomatic relief of digestive disorders, sensation of fullness and indigestion and to support the liver function, after serious conditions have been excluded by a medical doctor.</p> <p>New!</p> | <p>Herbal preparations</p> <ul style="list-style-type: none"> a) Comminuted herbal substance for herbal tea b) Powdered herbal substance c) Dry extract (DER 20-70:1), extraction solvent acetone d) Dry extract (DER 30-40:1), extraction solvent ethanol 96% (V/V) e) Dry extract (DER 20-35:1), extraction solvent ethyl acetate f) Dry extract (DER 26-45:1), extraction solvent ethyl acetate g) Dry extract (DER 36-44:1), extraction solvent ethyl acetate h) Dry extract (DER 20-34:1), extraction solvent methanol 90% (V/V) i) Soft extract (DER 10-17:1), extraction solvent ethanol 60% (V/V) <p>New!</p> | <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in solid or liquid dosage forms for oral use</p> <p>New!</p> | <p>Adults Elderly</p> <p>New!</p> | <p>The use is not recommended due to lack of adequate data.</p> <p>New!</p> |
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| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|--|--|---|---|--|--|
| Sisymbrii officinalis herba Monograph Assessment report | Mouth and throat disorders Cough and cold | For the relief the symptoms of throat irritation such as hoarseness and dry cough. | Herbal preparations - Dry extract (DER 3.5-5.5:1), extraction solvent water - Dry extract (DER 6-8:1), extraction solvent water | Herbal preparations in solid dosage form for oromucosal use. Herbal preparation in liquid dosage form for oral use. | Oromucosal use: Children older than 6 years Adolescents Adults Oral use: Children older than 3 years Adolescents Adults | Oromucosal use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form). Oral use in children under 3 years of age is not recommended due to lack of adequate data and because medical advice should be sought. |
| Soiae Oleum raffinatum Monograph Assessment report | Skin disorders and minor wounds | For the symptomatic relief of dry skin conditions associated with mild recurrent eczema. | Herbal preparations Soya-bean oil, refined | Liquid dosage forms for use as a bath additive | Infants Children Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Solidaginis virgaureae herba Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine - as adjuvant in treatment of minor urinary complaints. | Herbal preparations - Comminuted herbal substance - Liquid extract (1:1) prepared with ethanol/water 25% (V/V) - Tincture (1:5 (V/V)) prepared with ethanol/water 45% (V/V) - Dry extract (5-7:1) prepared with ethanol/water 30 – 60% (V/V) | Solid or liquid dosage forms or herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| Species amarae Monograph Assessment report    | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations Combinations of the comminuted herbal substances (see combinations table in the monograph) | Comminuted herbal substances as herbal tea for oral use   | Adolescents (depending on the herbal substances) Adults Elderly  | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|---|---|---|---|--|
| Species digestivae Monograph Assessment report    | Gastro-intestinal disorders | Used for the symptomatic relief of mild dyspeptic / gastrointestinal disorders including bloating and flatulence. | Herbal preparations Combinations of the comminuted herbal substances (see combinations table in the monograph)  | Comminuted herbal substances as herbal tea for oral use   | Adolescents (depending on the herbal substances) Adults Elderly   | The use is not recommended due to lack of adequate data. |
| Species diuretiae Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations Combinations of the comminuted herbal substances (see combinations table in the monograph)  | Comminuted herbal substances as herbal tea for oral use | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Species sedativae Monograph Assessment report    | Mental stress and mood disorders | Used for relief of mild symptoms of mental stress and to aid sleep. | Herbal preparations Combinations of the comminuted herbal substances (see combinations table in the monograph)  | Comminuted herbal substances as herbal tea for oral use | Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Species sedativae Monograph Assessment report    | Sleep disorders and temporary insomnia | Used for relief of mild symptoms of mental stress and to aid sleep. | Herbal preparations Combinations of the comminuted herbal substances (see combinations table in the monograph)  | Comminuted herbal substances as herbal tea for oral use   | Adolescents Adults Elderly   | The use is not recommended due to lack of adequate data. |

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|--|------------------------------|---|--|--|---------------|---|
| <p>Symphyti radix</p> <p>Monograph</p> <p>Assessment report</p> | <p>Pain and inflammation</p> | <p>For the symptomatic relief of minor sprains and bruises.</p> | <p>Herbal preparations Liquid extract prepared by extraction with ethanol 65% (V/V) followed by partial evaporation and adjustment to a DER 2:1</p> | <p>Herbal preparations in semi-solid dosage forms for cutaneous use.</p> | <p>Adults</p> | <p>The use is not recommended due to lack of adequate data.</p> |
|--|------------------------------|---|--|--|---------------|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|--|---|---|----------------------------------|--|
| Tanaceti parthenii herba Monograph Assessment report | Pain and inflammation | For the prophylaxis of migraine headaches, after serious conditions have been excluded by a medical doctor. | Herbal preparation Powdered herbal substance | Herbal preparation in solid dosage forms for oral use. | Adults Elderly | The use is not recommended due to lack of adequate data. |
| Taraxaci folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal preparations - Dried leaves, comminuted - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Expressed juice from fresh leaves | Herbal preparations in liquid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Taraxaci officinalis radix Monograph Assessment report New! | Gastro-intestinal disorders | For the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence, and slow digestion). New! | Herbal preparations a) Comminuted dried root b) Expressed juice (DER 1:1) from fresh root subjected to a steam of ethanol c) Juice from fresh root d) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V New! f) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage form for oral use. New! | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. New! New! |
| Taraxaci officinalis radix Monograph Assessment report New! | Loss of appetite | For temporary loss of appetite. New! | Herbal preparations a) Comminuted dried root b) Expressed juice (DER 1:1) from fresh root subjected to a steam of ethanol New! | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage form for oral use. New! | Adolescents Adults Elderly | The use is not recommended due to lack of adequate data. New! |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|---|---|--|--|
| Taraxaci officinalis radix Monograph Assessment report   | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints | Herbal preparations <ul style="list-style-type: none"> a) Comminuted dried root b) Expressed juice (DER 1:1) from fresh root subjected to a steam of ethanol c) Juice from fresh root d) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V f)  | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid dosage form for oral use.  | Adolescents Adults Elderly   | The use is not recommended due to lack of adequate data. |
| Taraxaci radix cum herba Monograph Assessment report | Gastro-intestinal disorders | For the relief of symptoms related to mild digestive disorders (such as feeling of abdominal fullness, flatulence, and slow digestion). | Herbal preparations <ul style="list-style-type: none"> - Dried root with herb, comminuted - Dry extract (DER 5.6-8.4:1), extraction solvent ethanol 60% (V/V) - Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 30% (V/V) - Liquid extract (DER 0.75:1), extraction solvent ethanol 30% m/m - Expressed juice (DER 1:0.5-0.8), fresh flowering Taraxaci radix cum herba | Herbal preparations in solid or liquid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Taraxaci radix cum herba Monograph Assessment report | Loss of appetite | Used in temporary loss of appetite. | Herbal preparations <ul style="list-style-type: none"> - Dried root with herb, comminuted - Dry extract (DER 5.6-8.4:1), extraction solvent ethanol 60% (V/V) - Liquid extract (DER 1:0.9-1.1), extraction solvent ethanol 30% (V/V) - Liquid extract (DER 0.75:1), extraction solvent ethanol 30% m/m - Expressed juice (DER 1:0.5-0.8), fresh flowering Taraxaci radix cum herba | Herbal preparations in solid or liquid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

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|--|--|--|--|---|-------------------------------|---|
| <p>Taraxaci radix cum herba</p> <p>Monograph</p> <p>Assessment report</p> | <p>Urinary tract and genital disorders</p> | <p>Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</p> | <p>Herbal preparations Dried root with herb, comminuted</p> | <p>Herbal preparations in solid or liquid dosage forms for oral use. Comminuted herbal substance as herbal tea for oral use.</p> | <p>Adolescents Adults</p> | <p>The use is not recommended due to lack of adequate data.</p> |
|--|--|--|--|---|-------------------------------|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------|---|--|---|---|---|
| Thymi aetheroleum Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal preparation Essential oil | Herbal preparations in liquid dosage forms for oral use.  | Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Thymi aetheroleum Monograph Assessment report | Cough and cold | For the relief of symptoms in coughs and colds. | Herbal preparation Essential oil | Herbal preparations in liquid or semi-solid dosage forms for cutaneous use and use as a bath additive.  | Use as bath additive: Children older than 3 years Adolescents Adults Elderly Cutaneous use: Adults  | Use as bath additive: the use is not recommended due to lack of adequate data and because medical advice should be sought. Cutaneous use: the use is not recommended due to lack of adequate data. |

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|--|----------------|---|---|--|--|---|
| Thymi herba Monograph Assessment report | Cough and cold | Used as an expectorant in cough associated with cold. | Herbal preparations: a) Liquid extract (DER 1:1), extraction solvent ethanol 24% (V/V) b) Liquid extract (DER 1:1.16), extraction solvent glycerol 85% (m/m): ethanol 25% (m/m)(0.1:2) c) Liquid extract (1:2-2.5), extraction solvent ammonia solution 10% (m/m) : glycerol 85% (m/m) : ethanol 25% (V/V) : water (1:20:70:109) d) Tincture (1:10), extraction solvent ethanol 70% (V/V) e) Tincture (1:5), extraction solvent ethanol 70% (V/V) f) Soft extract (DER 5-8:1), extraction solvent ethanol 25-30% (V/V) g) Liquid extract fresh herb (DER 1:1.5-2.4), extraction solvent water (often referred as "expressed juice") h) Dry extract (DER 6-10:1), extraction solvent ethanol 70% (V/V) i) Dry extract (DER 1.6-2.4:1), extraction solvent ethanol 96% (V/V) j) Liquid extract (DER 1-4.5), extraction solvent ammonia solution 10% (m/m) : glycerol 85% (m/m) : ethanol 96% (V/V) : water (1.2:25:112:113) k) Dry extract (7-13:1), extraction solvent water j) Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Herbal preparations c) and g): Children older than 4 years Adolescents Adults Other preparations: Adolescents Adults | Children younger than 4 years: the use is not recommended because medical advice should be sought. Children from 4 to 12 years: the use is not recommended due to lack of adequate data. |
| | | | | | | |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------|--|--|---|---|---|
| Thymi herba and Primulae radix Monograph Assessment report | Cough and cold | Traditional herbal medicinal product used as an expectorant in cough associated with cold. | <p>Herbal preparations</p> <p>a) Dry extract from Thyme (DER 6-10:1), extraction solvent ethanol 70% V/V and dry extract from Primula root (DER 3.5-4.5:1), extraction solvent water</p> <p>b) Liquid extract from Thyme (DER 1:2-2.5), extraction solvent ammonia solution 10% m/m: glycerol 85% m/m: ethanol 90% V/V: water (1:20:70:109) and soft extract from Primula root (DER 3-7:1), extraction solvent methanol: water: ammonia solution 26% (50:49.5:0.5)</p> <p>c) Liquid extract from Thyme (DER 1:2-2.5), extraction solvent ammonia solution 10% m/m: glycerol 85% m/m: ethanol 90% V/V: water (1:20:70:109) and soft extract from Primula root (DER 1-2:1), extraction</p> <p>d) Dry extract from Thyme (DER 4.5-7:1), extraction solvent methanol 25% V/V and dry extract from Primula root (DER 4-6:1), extraction solvent water</p> <p>e) Liquid extract from Thyme (DER 1:2-3), extraction solvent ethanol 20% V/V and liquid extract from Primula root (DER 1:2-3), extraction solvent ethanol 15% V/V</p> <p>f) Soft extract from Thyme (DER 5-7:1), extraction solvent methanol 25% V/V and soft extract from Primula root (DER 6-10:1), extraction solvent water</p> <p>g) Liquid extract from Thyme (DER 1:2-2.5), extraction solvent ammonia solution 10% m/m: glycerol 85% m/m: ethanol 90% V/V: water (1:20:70:109) and tincture from Primula root (Ratio herbal substance to extraction solvent 1:5), extraction solvent ethanol 50% V/V</p> <p>h) Liquid extract from Thyme (DER 1:2-2.5), extraction solvent ammonia solution 10% m/m: glycerol 85% m/m: ethanol 90% V/V: water (1:20:70:109) and liquid extract from Primula root (DER 1:2-2.5), extraction solvent ethanol 70% m/m</p> <p>i) Liquid extract from the mixture of Thyme (DER 1:3.3) and Primula root (DER 1:2-4.6), extraction solvent water</p> | Herbal preparations in liquid or solid dosage forms for oral use. | Preparations c,g,h : Children older than 4 years All preparations: Adolescents Adults | Children younger than 4 years: the use is not recommended because medical advice should be sought. Children from 4 to 12 years: the use is not recommended due to lack of adequate data. (preparations a,b,d,e,f,i) |
| Tiliae flos Monograph Assessment report | Cough and cold | For the relief of symptoms of common cold. | <p>Herbal preparations</p> <ul style="list-style-type: none"> - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) | Comminuted herbal substance as herbal tea for oral use. | Children older than 4 years Adolescents Adults | The use in children under 4 years of age has not been established due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|----------------------------------|--|---|---|--------------------------|--|
| Tiliae flos Monograph Assessment report | Mental stress and mood disorders | For the relief of mild symptoms of mental stress. | Herbal preparations - Comminuted herbal substance - Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) - Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults | The use in children under 12 years of age has not been established due to lack of adequate data. |
| Tomentillae rhizoma Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild diarrhoea. | Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) d) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) e) Dry extract (DER 3.5-4.5:1), extraction solvent ethanol 60% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations b), c), d), e) in liquid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Tomentillae rhizoma Monograph Assessment report | Pain and inflammation | For the symptomatic treatment of minor inflammations of the oral mucosa. | Herbal preparations a) Comminuted herbal substance: as infusion: 1.3-2 g per 100 ml of water as decoction: 0.8-3 g per 100 ml of water b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) | Comminuted herbal substance for infusion or decoction preparation for oromucosal use. Herbal preparation b) in liquid dosage forms for oromucosal use. | Adults | The use is not recommended due to lack of adequate data. |
| Trigonellae foenugraeci semen Monograph Assessment report | Skin disorders and minor wounds | Used for the symptomatic treatment of minor inflammations of the skin. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations c) Powdered herbal substance | Herbal substance or powdered herbal substance for infusion for cutaneous use. | Adults Elderly | The use is not recommended due to lack of adequate safety data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------------------|---|---|--|---|---|
| Trigonellae foenugraeci semen Monograph Assessment report    | Loss of appetite | Used in temporary loss of appetite. | Herbal substance As defined in the Ph. Eur. monograph Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 4:1), extraction solvent ethanol 20% (V/V) d) Soft extract (DER 5-6:1), extraction solvent ethanol 60% (V/V)  | Herbal substance or comminuted herbal as herbal tea for oral use. Herbal preparations in solid dosage forms for oral use. | Adults Elderly   | The use is not recommended due to lack of adequate safety data. |
| Urticae folium Monograph Assessment report | Pain and inflammation | For relief of minor articular pain. | Herbal substance Cut dried leaves Herbal preparations - Comminuted herbal substance - Liquid extracts (1:5) prepared with 96% ethanol (V/V):water:wine 16.5% (V/V) (1.65:1.35:7) - Dry extract (4.7-6:1), extraction solvent: water, - Dry extract (5-10:1), extraction solvent: water - Dry extract (8-10:1), extraction solvent: ethanol 50% (V/V) | Solid or liquid dosage forms or as an herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| Urticae folium Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal substance cut dried leaves Herbal preparations - Comminuted herbal substance - Liquid extracts (1:5) prepared with 96% ethanol (V/V):water:wine 16.5% (V/V) (1.65:1.35:7) - Dry extract (4.7-6:1), extraction solvent: water - Dry extract (5-10:1), extraction solvent: water - Dry extract (8-10:1), extraction solvent: ethanol 50% (V/V) | Solid or liquid dosage forms or as an herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| Urticae herba Monograph Assessment report | Urinary tract and genital disorders | Used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. | Herbal substance Dried cut or fragmented aerial parts of the plant collected or harvested during the flowering period | Liquid dosage forms or as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|-------------------------------------|---|---|--|--|--|
| <u>Urticae herba</u> <u>Monograph</u> <u>Assessment report</u> | Pain and inflammation | For relief of minor articular pain. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Expressed juice (1:0.5-1.1) from fresh herb - Expressed juice (1.36-1.96:1) from fresh herb - Liquid extract (1:1), extraction solvent: ethanol 25% (V/V) - Liquid extract (1:1.8-2.2), extraction solvent: ethanol 30% (V/V) - Tincture (1:5), extraction solvent: ethanol 45% (V/V) - Dry extract (5-10:1), extraction solvent: water | Liquid dosage forms or as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| <u>Urticae herba</u> <u>Monograph</u> <u>Assessment report</u> | Skin disorders and minor wounds | Used in seborrhoeic skin conditions. | Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Expressed juice (1:0.5-1.1) from fresh herb - Expressed juice (1.36-1.96:1) from fresh herb - Liquid extract (1:1), extraction solvent: ethanol 25% (V/V) - Liquid extract (1:1.8-2.2), extraction solvent: ethanol 30% (V/V) - Tincture (1:5), extraction solvent: ethanol 45% (V/V) - Dry extract (5-10:1), extraction solvent: water | Liquid dosage forms or as herbal tea for oral use. | Adolescents Adults | The use is not recommended due to lack of adequate experience. |
| <u>Uvae ursi folium</u> <u>Monograph</u> <u>Assessment report</u> | Urinary tract and genital disorders | For relief of symptoms of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent urination in women, after serious conditions have been excluded by a medical doctor. | Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 3.5-5.5:1), extraction solvent ethanol 60% (V/V), containing 23.5-29.3% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry) d) Dry extract (DER 2.5-4.5:1), extraction solvent water, containing 20-28% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry) e) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) | Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. | Female adults Elderly   | The use is not recommended because of concerns requiring medical advice. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|--|---|--|--|---|--|--|
| Vaccinii macrocarpi fructus Monograph Assessment report   | Urinary tract and genital disorders   | For relief of symptoms of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent urination in women, after serious conditions have been excluded by a medical doctor.  | Herbal preparations Expressed juice from the fresh fruit (DER 1: 0.6-0.9)  | Herbal preparations in liquid dosage forms for oral use.  | Female adults Elderly   | The use is not recommended because data is not sufficient and medical advice should be sought. |
| Vaccinii macrocarpi fructus Monograph Assessment report   | Urinary tract and genital disorders   | For prevention of recurrent uncomplicated lower urinary tract infections in women, after serious conditions have been excluded by a medical doctor.  | Herbal preparations Expressed juice from the fresh fruit (DER 1: 0.6-0.9)  | Herbal preparations in liquid dosage forms for oral use.  | Female adults Elderly   | The use is not recommended because data is not sufficient and medical advice should be sought. |
| Valerianae aetheroleum Monograph Assessment report | Sleep disorders and temporary insomnia | Used to aid sleep. | Herbal preparation essential oil | Herbal preparations in liquid dosage forms for oral use. Herbal preparations in liquid dosage forms for use as bath additive. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

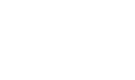
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|--|---|--|--|---|-------------------------------|---|
| <p>Valerianae aetheroleum</p> <p>Monograph</p> <p>Assessment report</p> | <p>Mental stress and mood disorders</p> | <p>Relief of mild symptoms of mental stress.</p> | <p>Herbal preparation essential oil</p> | <p>Herbal preparations in liquid dosage forms for oral use.</p> <p>Herbal preparations in liquid dosage forms for use as bath additive.</p> | <p>Adolescents Adults</p> | <p>The use is not recommended due to lack of adequate data.</p> |
|--|---|--|--|---|-------------------------------|---|

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|--------------------|---|---|--------------------------|--|
| Valerianae radix Monograph Assessment report | Sleep disorders and temporary insomnia | Used to aid sleep. | <p>Herbal preparations</p> <ul style="list-style-type: none"> a) Comminuted herbal substance b) Powdered herbal substance c) Expressed juice from fresh root (1:0.60-0.85) d) Dry extract (DER 4-6:1), extraction solvent: water e) Liquid extract (DER 1:4-6), extraction solvent: water f) Dry extract (DER 4-7:1), extraction solvent: methanol 45% (V/V) g) Dry extract (DER 5.3-6.6:1), extraction solvent: methanol 45% (m/m) h) Liquid extract (DER 1:7-9), extraction solvent: sweet vine i) Liquid extract (DER 1:1), extraction solvent: ethanol 60% (V/V) j) Tincture (ratio of herbal substance to extraction solvent 1:8), extraction solvent: ethanol 60% (V/V) k) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent: ethanol 56% l) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70% (V/V) m) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 60-80% (V/V) n) Dry extract (DER 5.5-7.4:1), extraction solvent: ethanol 85% (m/m) | <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparation in liquid or solid dosage forms for oral use.</p> <p>Comminuted herbal substance for use as bath additive (prep. a).</p> | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|----------------------------------|---|---|---|--------------------------|--|
| Valerianae radix Monograph Assessment report | Mental stress and mood disorders | Relief of mild symptoms of mental stress. | <p>Herbal preparations</p> <ul style="list-style-type: none"> a) Comminuted herbal substance b) Powdered herbal substance c) Expressed juice from fresh root (1:0.60-0.85) d) Dry extract (DER 4-6:1), extraction solvent: water e) Liquid extract (DER 1:4-6), extraction solvent: water f) Dry extract (DER 4-7:1), extraction solvent: methanol 45% (V/V) g) Dry extract (DER 5.3-6.6:1), extraction solvent: methanol 45% (m/m) h) Liquid extract (DER 1:7-9), extraction solvent: sweet vine i) Liquid extract (DER 1:1), extraction solvent: ethanol 60% (V/V) j) Tincture (ratio of herbal substance to extraction solvent 1:8), extraction solvent: ethanol 60% (V/V) k) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent: ethanol 56% l) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70% (V/V) m) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 60-80% (V/V) n) Dry extract (DER 5.5-7.4:1), extraction solvent: ethanol 85% (m/m) | <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparation in liquid or solid dosage forms for oral use.</p> <p>Comminuted herbal substance for use as bath additive (prep. a).</p> | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|--------------------|--|--|---|--|
| Valerianae radix and Lupuli flos Monograph Assessment report | Sleep disorders and temporary insomnia | Used to aid sleep. | <p>Herbal preparations used in fixed combinations of</p> <p>Liquid extracts:</p> <ul style="list-style-type: none"> a) Liquid extract (DER 1:6.3) from a mixture of valerian root-hop strobile (1:1), extraction solvent ethanol 40% (V/V) b) Mixture (1:1) of valerian root tincture (DER 1:10-11), extract solvent ethanol 58% (V/V) and hop strobile tincture (DER 1:12-13), extract solvent ethanol 65% V/V <p>Dry extracts:</p> <ul style="list-style-type: none"> a) Dry extracts of valerian root (DER 4-6:1), extraction solvent water and hop strobile (DER 3-6:1), extraction solvent water b) Dry extracts of valerian root (DER 5-7:1), extraction solvent methanol 45% m/m and hop strobile (DER 5-7:1), extraction solvent water c) Dry extracts of valerian root (DER 4-5:1), extraction solvent ethanol 60% (V/V) and hop strobile (DER 5-9:1), extraction solvent water d) Dry extracts of valerian root (DER 4-7:1), extraction solvent methanol 45% (V/V) and hop strobile (DER 4-8:1), extraction solvent ethanol 40% (V/V) e) Dry extracts of valerian root (DER 3-7:1), extraction solvent ethanol 70% (V/V) and hop strobile (DER 4-8:1), extraction solvent ethanol 40% (V/V) f) Dry extracts of valerian root (DER 6-7:1), extraction solvent ethanol 70% (V/V) and hop strobile (DER 11-14:1), extraction solvent ethanol 96% (V/V) g) Dry extracts of valerian root (DER 5-8:1), extraction solvent ethanol 85% (V/V) and hop strobile (DER 9-11:1), extraction solvent ethanol 90% (V/V) | Herbal preparations in solid or liquid dosage forms for oral use.  | Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|----------------------------------|--|--|--|--|--|
| Valerianae radix and Lupuli flos Monograph Assessment report | Mental stress and mood disorders | For relief of mild symptoms of mental stress. | <p>Herbal preparations used in fixed combinations of</p> <p>Liquid extracts:</p> <ul style="list-style-type: none"> a) Liquid extract (DER 1:6.3) from a mixture of valerian root-hop strobile (1:1), extraction solvent ethanol 40% (V/V) b) Mixture (1:1) of valerian root tincture (DER 1:10-11), extract solvent ethanol 58% (V/V) and hop strobile tincture (DER 1:12-13), extract solvent ethanol 65% V/V <p>Dry extracts:</p> <ul style="list-style-type: none"> a) Dry extracts of valerian root (DER 4-6:1), extraction solvent water and hop strobile (DER 3-6:1), extraction solvent water b) Dry extracts of valerian root (DER 5-7:1), extraction solvent methanol 45% m/m and hop strobile (DER 5-7:1), extraction solvent water c) Dry extracts of valerian root (DER 4-5:1), extraction solvent ethanol 60% (V/V) and hop strobile (DER 5-9:1), extraction solvent water d) Dry extracts of valerian root (DER 4-7:1), extraction solvent methanol 45% (V/V) and hop strobile (DER 4-8:1), extraction solvent ethanol 40% (V/V) e) Dry extracts of valerian root (DER 3-7:1), extraction solvent ethanol 70% (V/V) and hop strobile (DER 4-8:1), extraction solvent ethanol 40% (V/V) f) Dry extracts of valerian root (DER 6-7:1), extraction solvent ethanol 70% (V/V) and hop strobile (DER 11-14:1), extraction solvent ethanol 96% (V/V) g) Dry extracts of valerian root (DER 5-8:1), extraction solvent ethanol 85% (V/V) and hop strobile (DER 9-11:1), extraction solvent ethanol 90% (V/V) | Herbal preparations in solid or liquid dosage forms for oral use.  | Adolescents Adults Elderly  | The use is not recommended due to lack of adequate data. |
| Verbasci flos Monograph Assessment report | Cough and cold | To relieve symptoms of sore throat associated with dry cough and cold. | <p>Herbal substance As defined in the Ph. Eur. monograph.</p> <p>Herbal preparation Comminuted herbal substance</p> | Herbal substance or comminuted herbal substance as herbal tea for oral use.  | Adolescents Adults Elderly   | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|--|--|---|---|---|--|
| Verbenae citriodorae folium Monograph Assessment report    | Gastro-intestinal disorders | For symptomatic treatment of mild gastrointestinal complaints including bloating and flatulence. | Herbal substance As defined in the Ph. Eur. monograph. Herbal preparation Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults Elderly    | The use is not recommended due to lack of adequate data. |
| Verbenae citriodorae folium Monograph Assessment report    | Mental stress and mood disorders | For relief of mild symptoms of mental stress and to aid sleep. | Herbal substance As defined in the Ph. Eur. monograph. Herbal preparation Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults Elderly    | The use is not recommended due to lack of adequate data. |
| Verbenae citriodorae folium Monograph Assessment report    | Sleep disorders and temporary insomnia | For relief of mild symptoms of mental stress and to aid sleep. | Herbal substance As defined in the Ph. Eur. monograph. Herbal preparation Comminuted herbal substance  | Comminuted herbal substance as herbal tea for oral use. | Adolescents Adults Elderly    | The use is not recommended due to lack of adequate data. |

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|---|---------------------------------|--|--|---|-----------------------|--|
| Violae herba cum flore Monograph Assessment report | Skin disorders and minor wounds | For symptomatic treatment of mild seborrhoeic skin conditions. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Violae herba cum flore Monograph Assessment report | Skin disorders and minor wounds | For symptomatic treatment of mild seborrhoeic skin conditions. | Herbal preparation Comminuted herbal substance | Comminuted herbal substance as herbal tea for infusion preparation for cutaneous use. | Adolescents Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-------------------------|---|--|---|--------------------------|---|
| Vitis viniferae folium Monograph Assessment report | Circulatory disorders | To relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. | Herbal preparations - Comminuted herbal substance as herbal tea - Powdered herbal substance - Soft extract (DER 2.5-4:1); extraction solvent water | Comminuted herbal substance as herbal tea for oral use. Herbal preparation in solid dosage forms for oral use. Herbal preparation in semi-solid dosage forms for cutaneous use. | Adults | The indication is not relevant to children and adolescents. |
| Vitis viniferae folium Monograph Assessment report | Circulatory disorders | For symptomatic relief of itching and burning associated with haemorrhoids. | Herbal preparations - Comminuted herbal substance as herbal tea - Powdered herbal substance | Comminuted herbal substance as herbal tea for oral use. Herbal preparation in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |
| Vitis viniferae folium Monograph Assessment report | Circulatory disorders | For symptomatic treatment of cutaneous capillary fragility. | Herbal preparations - Comminuted herbal substance as herbal tea - Powdered herbal substance | Comminuted herbal substance as herbal tea for oral use. Herbal preparation in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |

| | Therapeutic area | Indication | Herbal substances and/or preparations referred in the monograph | Dosage form and method of administration | Target population | Justification for limited use |
|---|-----------------------------|---|--|---|--|--|
| Zingiberis rhizoma Monograph Assessment report | Gastro-intestinal disorders | For the symptomatic relief of motion sickness. | Herbal preparation Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Children older than 6 years Adolescents Adults | The use is not recommended due to lack of adequate data. |
| Zingiberis rhizoma Monograph Assessment report | Gastro-intestinal disorders | For symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence. | Herbal preparation Powdered herbal substance | Herbal preparations in solid dosage forms for oral use. | Adults | The use is not recommended due to lack of adequate data. |