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Committee on Herbal Medicinal Products (HMPC)

HMPC monographs: Overview of recommendations for the uses of herbal medicinal products in the paediatric population

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Introduction

The purpose of this list is to provide an overview of the recommendations for use of the herbal preparations in the paediatric population as set out in the HMPC monographs. The list summarises the indications and any limitations of use in children as assessed by the HMPC.

The age range and use of herbal medicinal products, within this special population of patients, are frequently discussed by healthcare professionals. The purpose of this overview, is to provide a summary of the information from the monographs for ease of reference.

The list pertains to the specific substances/preparations¹ as mentioned in the European Union monographs and not to other categories of herbal products such as food or food supplements.

¹ Ethanol is often used as extraction solvent in the manufacture of herbal medicinal products. Solvents specified for herbal preparations as listed here do not reflect the ethanol content in the finished product. The final amount is calculated by the producer and appears on the label and in the package leaflet of each individual product. For more information please consult the Reflection paper on ethanol content in HMP and THMP used in children ([EMA/HMPC/85114/2008](http://www.ema.europa.eu/EMA/HMPC/85114/2008)).

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The list is divided into two groups of herbal medicinal products:

- well-established use (marketing authorisation, WEU): demonstrated with sufficient safety and efficacy data (page 13-19);
- traditional use (simplified registration, TU): accepted on the basis of sufficient safety data and plausible efficacy (page 20-72).

The monographs are generally applied within the EU and are taken into account by Member States when examining an application. Member States are not obliged to follow the monographs and it is possible that a Member State, with a due justification, will choose not to adhere to a specific monograph.

The list is derived from information in the monographs as adopted.

For further information reference should be made to the specific monographs and assessment reports.

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Herbal substances with Final European Union herbal monographs (alphabetical order):

A	Cinnamomi cortex	G	Melaleuca alternifoliae aetheroleum	Psyllii semen
Absinthii herba	Colae semen	Gentianae radix	Meliloti herba	Q
Agni casti fructus TU WEU	Curcumae longae rhizoma	Ginkgo folium TU WEU	Melissae folium	Quercus cortex
Agrimoniae herba	Curcumae xanthorrhizae rhizoma	H	Menthae piperitae aetheroleum TU WEU	R
Agropyri repentis rhizoma	Cynarae folium	Hamamelidis cortex	Menthae piperitae folium	Rhamni purshianae cortex
Aloe	E	Hamamelidis folium	Millefolii flos	Rhei radix
Althaeae radix	Echinaceae angustifoliae radix	Hamamelidis folium et cortex aut ramunculus destillatum	Millefolii herba	Rhodiolae roseae rhizoma et radix
Anisi aetheroleum	Echinaceae pallidae radix	Harpagophyti radix	Myrtilli fructus recens	Ribis nigri folium
Anisi fructus	Echinaceae purpureae herba TU WEU	Hederae helicis folium	Myrtilli fructus siccus	Rosae flos
Arctii radix	Echinaceae purpureae radix	Hippocastani cortex	Myrrha (Commiphora molmol)	Rosmarini aetheroleum
Arnicae flos	Eleutherococci radix	Hippocastani semen TU WEU	O	Rosmarini folium
Avenae fructus	Epilobii herba	Hyperici herba TU WEU	Oenotherae biennis oleum	Rubi idaei folium
Avenae herba	Eschscholziae herba	J	Oleae folium	Rusci aculeati rhizoma
B	Equiseti herba	Juglandis folium	Ononidis radix	S
Betulae folium	Eucalypti aetheroleum	Juniperi aetheroleum	Origanii dictamni herba	Sabalis serrulatae fructus
Boldi folium	F	Juniperi pseudo-fructus	Orthosiphonis folium	Salicis cortex TU WEU
Bursae pastoris herba	Filipendulae ulmariae flos	L	P	Salviae officinalis folium
C	Filipendulae ulmariae herba	Lavandulae aetheroleum	Panax ginseng radix	Sambuci flos
Calendulae officinalis flos	Foeniculi amari fructus	Lavandulae flos	Passiflorae herba	Sennae folium
Camelliae sinensis non fermentatum folium	Foeniculi amari fructus aetheroleum	Leonuri cardiaca herba	Phaseoli fructus sine semine	Sennae fructus
Capsici fructus	Foeniculi dulcis fructus	Lichen islandicus	Pilosellae herba cum radice	Sisymbrii officinalis herba
Caryophylli floris aetheroleum	Foenugraeci semen (Trigonella foenum-graecum)	Lini semen TU WEU	Plantaginis lanceolatae folium	Solidaginis virgaureae herba
Carvi aetheroleum	Frangulae cortex	Lupuli flos	Plantaginis ovatae semen	Symphyti radix
Carvi fructus	Fraxini folium	M	Plantaginis ovatae seminis tegumentum	T
Centaurii herba	Fucus vesiculosus thallus	Mate folium	Polypodii rhizoma	Tanacetii parthenii herba
Chamomillae romanae flos	Fumariae herba	Matricariae flos	Primulae flos	Taraxaci folium
Cimicifugae racemosae rhizoma		Matricariae aetheroleum	Primulae radix	Taraxaci radix cum herba
Cinnamomi corticis aetheroleum		Marrubii herba		Thymi aetheroleum

[Thymi herba](#)

[Tiliae flos](#)

[Tormentillae rhizoma](#)

U

[Urticae folium](#)

[Urticae herba](#)

[Uvae ursi folium](#)

V

Valerianae radix [TU](#) [WEU](#)

Valerianae radix and Lupuli
flos [TU](#) [WEU](#)

[Verbasci flos](#)

[Violae herba cum flore](#)

Vitis viniferae folium [TU](#) [WEU](#)

Z

Zingiberis rhizoma [TU](#) [WEU](#)

Herbal substances with Final European Union herbal monographs (according to therapeutic areas):

[ANTI-DEMENTIA DRUGS](#)

[CIRCULATORY DISORDERS](#)

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[SLEEP DISORDERS AND TEMPORARY INSOMNIA](#)

[URINARY TRACT AND GENITAL DISORDERS](#)

ANTI-DEMENTIA DRUGS

G	Ginkgo folium WEU
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CIRCULATORY DISORDERS

G	Ginkgo folium TU
H	Hamamelidis cortex , Hamamelidis folium , Hippocastani cortex , Hippocastani semen TU WEU
L	Leonuri cardiaca herba
M	Meliloti herba , Myrtilli fructus recens
Q	Quercus cortex
R	Rosmarini aetheroleum , Rosmarini folium , Rusci aculeati rhizoma
V	Vitis viniferae folium TU WEU

CONSTIPATION

A	Aloe
F	Frangulae cortex
L	Lini semen
P	Plantaginis ovatae semen , Plantaginis ovatae seminis tegumentum , Polypodii rhizoma , Psyllii semen
R	Rhamni purshianae cortex , Rhei radix
S	Sennae folium , Sennae fructus

COUGH AND COLD

A	Anisi aetheroleum , Anisi fructus
E	Echinaceae angustifoliae radix , Echinaceae pallidae radix , Echinaceae purpureae herba , Echinaceae purpureae radix , Eucalypti aetheroleum
F	Filipendulae ulmariae flos , Filipendulae ulmariae herba , Foeniculi amari fructus , Foeniculi amari fructus aetheroleum , Foeniculi dulcis fructus
H	Hederae heliis folium
M	Marrubii herba , Matricariae flos , Menthae piperitae aetheroleum
O	Origani dictamni herba
P	Polypodii rhizoma , Primulae flos , Primulae radix
S	Salicis cortex , Sambuci flos
T	Thymi aetheroleum , Thymi herba , Tiliae flos
V	Verbasci flos

EYE DISCOMFORT

H	Hamamelidis folium et cortex aut ramunculus destillatum
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FATIGUE AND WEAKNESS

C	Camelliae sinensis non fermentatum folium , Colae semen ,
E	Eleutherococci radix
M	Mate folium
P	Panax ginseng radix

GASTROINTESTINAL DISORDERS	
A	Absinthii herba , Agrimoniae herba , Althaeae radix , Anisi aetheroleum , Anisi fructus
B	Boldi folium
C	Carvi aetheroleum , Carvi fructus , Centaurei herba , Chamomillae romanae flos , Cinnamomi cortex , Cinnamomi corticis aetheroleum , Curcumae longae rhizoma , Curcumae xanthorrhizae rhizoma , Cynarae folium
F	Foeniculi amari fructus , Foeniculi dulcis fructus , Fucus vesiculosus thallus , Fumariae herba
G	Gentianae radix
H	Harpagophyti radix , Hyperici herba
J	Juniperi aetheroleum , Juniperi pseudo-fructus
L	Lini semen
M	Marrubii herba , Matricariae flos , Melissae folium , Menthae piperitae aetheroleum , Menthae piperitae folium , Millefolii flos , Millefolii herba , Myrtilli fructus siccus
O	Origani dictamni herba
Q	Quercus cortex
R	Rosmarini aetheroleum , Rosmarini folium , Rubi idaei folium
S	Salviae officinalis folium
T	Taraxaci radix cum herba , Tormentillae rhizoma
Z	Zingiberis rhizoma TU WEU

LOSS OF APPETITE	
A	Absinthii herba , Arctii radix
C	Centaurei herba
F	Foenugraeci semen
G	Gentianae radix
H	Harpagophyti radix
L	Lichen islandicus
M	Marrubii herba , Millefolii flos , Millefolii herba
T	Taraxacum radix cum herba

MENTAL STRESS AND MOOD DISORDERS

A	Avenae herba
E	Eschscholziae herba
H	Hyperici herba TU WEU
L	Lavandulae aetheroleum , Lavandulae flos , Leonuri cardiaca herba , Lupuli flos
M	Melissae folium
P	Passiflorae herba
R	Rhodiola roseae rhizoma et radix
T	Tiliae flos
V	Valerianae radix TU WEU , Valerianae radix and Lupuli flos

MOUTH AND THROAT DISORDERS

A	Agrimoniae herba , Althaeae radix
C	Calendula officinalis flos , Caryophylli aetheroleum
H	Hamamelidis cortex , Hamamelidis folium
L	Lichen islandicus
M	Matricariae flos , Melaleuca alternifoliae aetheroleum , Myrrha , Myrtilli fructus siccus
P	Plantaginis lanceolatae folium
R	Rosae flos , Rubi idaei folium
S	Salviae officinalis folium , Sisymbrii officinalis herba

PAIN AND INFLAMMATION

C	Capsici fructus
E	Eucalypti aetheroleum
F	Filipendulae ulmariae flos , Filipendulae ulmariae herba , Fraxini folium
H	Harpagophyti radix
J	Juniperi aetheroleum
M	Meliloti herba , Menthae piperitae aetheroleum TU WEU
Q	Quercus cortex
R	Ribis nigri folium
S	Salicis cortex TU WEU
T	Tanaceti parthenii herba , Tormentillae rhizoma
U	Urticae herba , Urticae folium

SKIN DISORDERS AND MINOR WOUNDS

A	Agrimoniae herba , Arctii radix , Arnicae flos , Avenae fructus
C	Calendula officinalis flos
E	Echinaceae purpureae herba
F	Foenugraeci semen
H	Hamamelidis cortex , Hamamelidis folium , Hamamelidis folium et cortex aut ramunculus destillatum , Hyperici herba
J	Juglandis folium
M	Matricariae flos , Melaleucaae alternifoliae aetheroleum , Menthae piperitae aetheroleum , Millefolii flos , Millefolii herba , Myrrha
O	Oenotherae biennis folium , Origani dictamni herba
R	Rosae flos
S	Salviae officinalis folium
U	Urticae herba
V	Violae herba cum flore

SLEEP DISORDERS AND TEMPORARY INSOMNIA

A	Avenae herba
E	Eschscholziae herba
L	Lavandulae aetheroleum , Lavandulae flos , Lupuli flos
M	Melissae folium
P	Passiflorae herba
R	Rhodiolae roseae rhizoma et radix
V	Valerianae radix TU WEU , Valerianae radix and Lupuli flos TU WEU

URINARY TRACT AND GENITAL DISORDERS

A	Agni casti fructus TU WEU , Agropyri repentis rhizoma , Arctii radix
B	Betulae folium , Bursae pastoris herba
C	Cimicifugae racemosae rhizoma
E	Equiseti herba
F	Foeniculi amari fructus , Foeniculi dulcis fructus , Fraxini folium
J	Juniperi aetheroleum , Juniperi pseudo-fructus
M	Mate folium , Millefolii flos , Millefolii herba
O	Oleae folium , Ononidis radix , Orthosiphonis folium
P	Phaseoli fructus sine semine
R	Ribis nigri folium , Rubi idaei folium
S	Solidaginis virgaureae herba
T	Taraxaci folium , Taraxaci radix cum herba
U	Urticae herba , Urticae folium , Uvae ursi folium

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.
Aloe Monograph Assessment report	Constipation	For short-term use in cases of occasional constipation.	Herbal substance Concentrated and dried juice of the leaves, standardised Herbal preparation Standardised Herbal preparations thereof	Solid or liquid 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 a) Soft extract (DER 4-7:1), standardised to 2.0–2.78% total capsaicinoids, extraction solvent ethanol 80% (V/V) b) Soft extract (DER 1.5–2.5:1), extraction solvent ethanol 96% (V/V) c) 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 racemosae rhizoma Monograph Assessment report	Urinary tract and genital disorders	For the relief of menopausal complaints (such as hot flushes and profuse sweating).	Herbal preparations -Dry extract (DER 5-10:1), extraction solvent ethanol 58% (V/V) -Dry extract (DER 4.5-8.5:1), extraction solvent ethanol 60% (V/V) -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 use is not relevant because the indication does not occur in 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 substance Dried, whole or fragmented bark of the stems and branches, standardised Herbal preparation Standardised herbal preparations thereof	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is contraindicated.
Ginkgo folium Monograph Assessment report	Anti-dementia drugs	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/m 3	Herbal preparations in solid or liquid dosage forms for oral use.	Adults	The use is not relevant because the indication does not occur in 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 over 2 years of age Adolescents Adults Elderly	Children under 2 years: the use is contraindicated.
Hippocastani semen Monograph Assessment report	Circulatory disorders	For treatment of chronic venous insufficiency.	Herbal preparations -Dry extracts (40-80% (V/V) ethanol) standardised to contain 16-28% triterpene glycosides, calculated as aescin (photometric method) -Extract (standardised to a content of 50 mg triterpene glycosides calculated as aescin)	Herbal preparations in modified or immediate release dosage forms for oral use.	Adults	The use is not relevant because the indication does not occur in 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
Hyperici herba Monograph Assessment report	Mental stress and mood disorders	For the treatment of mild to moderate depressive episodes (according to ICD-10).	Herbal preparations -Dry extract (DER 3-7: 1), extraction solvent methanol (80% (V/V)) -Dry extract (DER 3-6: 1), extraction solvent ethanol (80% (V/V))	Herbal preparation in solid dosage forms for oral use.	Adults	The use is not recommended due to lack of adequate data.
Hyperici herba Monograph Assessment report	Mental stress and mood disorders	For the short term treatment of symptoms in mild depressive disorders.	Herbal preparation Dry extract (DER 2.5-8: 1), extraction solvent ethanol (50-68% (V/V))	Herbal preparation in solid dosage forms for oral use.	Adults	The use is not recommended due to lack of adequate data.
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.
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 obtained by steam distillation from the fresh aerial parts of the flowering plant	Gastro-resistant capsules for oral use.	Children older than 8 years Adolescents Adults	The use is not recommended due to lack of adequate experience.
Menthae piperitae aetheroleum Monograph Assessment report	Pain and inflammation	For the symptomatic relief of mild tension type headache.	Herbal preparation Essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant	Liquid or semi-solid preparation for cutaneous 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
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.
Plantaginis ovatae seminis 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 seminis 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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
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.
Rhamni purshianae cortex Monograph Assessment report	Constipation	For short-term use in cases of occasional constipation.	Herbal substance: Dried, whole or fragmented bark, standardised Herbal preparations Standardised herbal preparations thereof	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is contraindicated.
Rhei radix Monograph Assessment report	Constipation	For short-term use in cases of occasional constipation.	Herbal substance Whole or cut, dried underground parts, standardised Herbal preparations Standardised herbal preparations thereof	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is contraindicated.
Salicis cortex Monograph Assessment report	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	Solid dosage form for oral use.	Adults	The use is not recommended because the product should only be used on medical advice and only in cases where other therapies failed to succeed.
Sennae folium Monograph Assessment report	Constipation	For short-term use in cases of occasional constipation.	Herbal substance Dried leaflets, standardised Herbal preparations Standardised herbal preparations thereof	Solid or liquid dosage forms for oral use.	Adolescents Adults	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
Sennae fructus Monograph Assessment report	Constipation	For short-term use in cases of occasional constipation.	Herbal substance Dried fruits, standardised Herbal preparations Standardised herbal preparations thereof	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is contraindicated.
Valerianae radix Monograph Assessment report	Mental stress and mood disorders	Relief of mild nervous tension.	Herbal preparation Extracts prepared with ethanol/water (ethanol 40 -70% (V/V))	Solid or liquid 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.	Herbal preparations Extracts prepared with ethanol/water (ethanol 40 -70% (V/V))	Solid or liquid 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.	Herbal preparations used in fixed combinations of -Dry extracts of valerian root (DER 4-8:1, methanol 45-51% m/m) and hop strobiles (DER 3-10:1, methanol 40-51% m/m) -Dry extracts of valerian root (DER 4-7:1, ethanol 70% (V/V)) and hop strobiles (DER 4-8:1, methanol 40% (V/V))	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is not recommended due to lack of adequate data.
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 use is not relevant because the indication does not occur in 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
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	Used in 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))	Herbal preparation in solid or liquid dosage forms or as herbal tea for oral use.	Adults	The use is not recommended due to lack of adequate data.
Absinthii herba Monograph Assessment report	Gastro-intestinal disorders	Used in mild dyspeptic/gastrointestinal disorders.	Herbal preparations -Comminuted herbal substance -Expressed juice from the fresh herb (1:0.5-0.9) -Tincture (1:5, ethanol 70% (V/V))	Herbal preparation in solid or liquid dosage forms or as herbal tea 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 -Powdered herbal substance -Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 58-60% (V/V) -Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70% (V/V) (manufacture under addition of calcium carbonate) -Dry extract (DER 7-13:1), extraction solvent: ethanol 60% m/m. -Dry extract (DER 10.0-18.5:1), extraction solvent: ethanol 50-52% m/m	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. 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.

	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 as herbal tea for oral use. 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 -Comminuted herbal substance -Liquid extract (DER 1: 1), extraction solvent ethanol 20-25% (V/V) -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.	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
Althaeae radix Monograph Assessment report	Mouth and throat disorders	For the symptomatic treatment of oral or pharyngeal irritation and associated dry cough.	Herbal preparations A-Comminuted herbal substance B-Liquid extract (1:19.5–23.5), extraction solvent water C- Macerate for preparation of syrup D-Dry extract (3–9:1), extraction solvent water 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 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	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, spasmodic gastrointestinal 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
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

	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 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.
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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
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.	All	
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	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 spasmodic disorders of the gastrointestinal tract.	Herbal substance Whole or fragmented, dried leaf Herbal preparations -Comminuted herbal substance -Dry extract (5:1, aqueous)	Herbal tea or in solid dosage forms 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
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.
Calendula officinalis 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 Whole or cut, dried, fully opened flowers, which have been detached from the receptacle, of the cultivated, double-flowered varieties. Herbal preparations -Liquid extract (1:1), extraction solvent ethanol 40-50% (V/V) -Liquid extract (1:1.8-2.2), extraction solvent ethanol 40-50% (V/V) -Tincture (1:5), extraction solvent ethanol 70-90% (V/V) -Liquid extract (1:10), extraction solvent fatty vegetable oil e.g. olive oil -Ointment (1:5–1:25), extraction solvent hardened vegetable fat, petroleum jelly -Comminuted herbal substance	Liquid or semi-solid dosage forms for cutaneous use.	Children older than 6 years Adolescents Adults	The use is not recommended due to lack of adequate experience.
Calendula officinalis flos Monograph Assessment report	Mouth and throat disorders	For the symptomatic treatment of minor inflammations in the mouth or the throat.	Herbal substance Whole or cut, dried, fully opened flowers, which have been detached from the receptacle, of the cultivated, double-flowered varieties. Herbal preparations -Liquid extract (1:1), extraction solvent ethanol 40-50% (V/V) -Liquid extract (1:1.8-2.2), extraction solvent ethanol 40-50% (V/V) -Tincture (1:5), extraction solvent ethanol 70-90% (V/V) -Liquid extract (1:10), extraction solvent fatty vegetable oil e.g. olive oil -Ointment (1:5–1:25), extraction solvent hardened vegetable fat, petroleum jelly -Comminuted herbal substance	Liquid or semi-solid dosage forms for oromucosal 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
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.	Adults (oral use) Infants, Children, Adolescents Adults (cutaneous use)	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.	i) Herbal substance As defined in the Ph. Eur. monograph. ii) 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.
Caryophylli 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 <i>Syzygium aromaticum</i> (L.) Merrill 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.
Caryophylli 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.) Merrill 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
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.
Chamomilla e 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.
Cinnamomi corticis aetheroleum Monograph Assessment report	Gastro-intestinal disorders	For the symptomatic treatment of mild, spasmodic gastrointestinal 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, spasmodic gastrointestinal 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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
Cinnamomi cortex Monograph Assessment report	Gastro-intestinal disorders	For the symptomatic treatment of mild diarrhoea.	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.
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.
Curcumae longae rhizoma Monograph Assessment report	Gastro-intestinal disorders	Used to increase bile flow for the relief of symptoms of indigestion (such as sensation of fullness, flatulence, and slow digestion).	Herbal preparations -Powdered herbal substance -Comminuted herbal substance -Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 70% (V/V) -Dry extract (DER 13-25:1), extraction solvent ethanol 96% (V/V) -Dry extract (DER 5.5-6.5:1), extraction solvent ethanol 50% (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 preparations in liquid or solid dosage forms for oral use.	Adults	The use is not recommended due to lack of adequate data.
Curcumae xanthorrhizae rhizoma 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 -Comminuted dried leaves for herbal tea -Powdered leaves -Dry extract (DER 2.5-7.5:1), extraction solvent water -Dry extract of fresh leaves (DER 15-35:1), extraction solvent water -Soft extract of fresh leaves (DER 15-30:1), extraction solvent water -Soft extract (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	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 supportive treatment of common cold.	Herbal preparations -Dry extract (4-8:1), extraction solvent: ethanol 50% (V/V) -Tincture (1:5), extraction solvent: ethanol 50% (V/V)	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is contraindicated.
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.
Echinaceae purpureae radix Monograph Assessment report	Cough and cold	For supportive treatment of common cold.	Herbal preparation Dry extract (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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
Eleutherococc 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 preparations -Comminuted herbal substance	Comminuted herbal substance as herbal tea for oral use.	Adults	The use is not relevant because the indication does not occur in children and adolescents.
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 -Comminuted herbal substance -Expressed juice (1:1.6-2.0) -Liquid extract (1:4-5) extraction solvent: ethanol 31.5% m/m -Liquid extract (1:5) extraction solvent: ethanol 96% (V/V)/water/sweet wine (16.5/13.5/70) m/m -Liquid extract (1:5.5) extraction solvent: sweet wine/ethanol 96% (V/V) (91/9) m/m -Dry extract (4-7:1) extraction solvent: water -Dry extract (7.5-10.5:1) extraction solvent: ethanol 70% (V/V)	Solid or liquid dosage forms or as herbal tea for oral use.	Adolescents Adults	The use is not recommended due to lack of adequate experience.
Eschscholziae herba Monograph Assessment report	Mental stress & mood disorders	For relief of mild symptoms of mental stress	Herbal preparations 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.
Eschscholziae herba Monograph Assessment report	Sleep disorders & temporary insomnia	Used to aid sleep.	Herbal preparations 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
Eucalypti aetheroleum Monograph Assessment report	Cough and cold	For relief of cough associated with cold.	Herbal preparations 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 and inhalation: Adolescents Adults. Cutaneous use Use as Bath additive: 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.
Eucalypti aetheroleum Monograph Assessment report	Pain and inflammation	For the symptomatic relief of localised muscle pain	Herbal preparations 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.
Filipendulae ulmariae flos Monograph Assessment report	Cough and cold	For the supportive treatment of common 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.
Filipendulae ulmariae flos Monograph Assessment report	Pain and inflammation	For the 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.

	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	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.
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.
Foenugraeci semen (Trigonella foenum-graecum) Monograph Assessment report	Skin disorders and minor wounds	Used for the symptomatic treatment of minor inflammations of the skin.	Herbal substance Herbal substance for infusion	Herbal substance for infusion 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
Foenugraeci semen (Trigonella foenum-graecum) Monograph Assessment report	Loss of appetite	Used in temporary loss of appetite.	Herbal substance Herbal substance for tea preparation Herbal preparations -Dry extract (DER 4:1), extraction solvent: ethanol 20% (V/V) -Soft extract (DER 5-6:1), extraction solvent: ethanol 60% (V/V)	Herbal substance as herbal tea for oral use. Herbal preparation in solid dosage form for oral use.	Adults	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.
Fumariae herba Monograph Assessment report	Gastro-intestinal disorders	Used to increase bile flow for the relief of symptoms of indigestion (such as sensation of fullness, flatulence and slow digestion).	Herbal preparations -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	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
Gentianae radix Monograph Assessment report	Gastro-intestinal disorders	Used in mild dyspeptic/gastrointestinal disorders.	Herbal preparations -Comminuted herbal substance -Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 53% (V/V) -Tincture (Ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) -Liquid extract (DER 1:1), extraction solvent ethanol 45% (V/V)	Comminuted herbal substance as 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.
Gentianae radix Monograph Assessment report	Loss of appetite	Used in temporary loss of appetite.	Herbal preparations -Comminuted herbal substance -Dry extract (DER 4.5-5.5:1), extraction solvent ethanol 53% (V/V) -Tincture (Ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) -Liquid extract (DER 1:1), extraction solvent ethanol 45% (V/V)	Comminuted herbal substance as 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.
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.
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.
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.

	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	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.
Hamamelidis folium 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.
Hamamelidis folium 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.
Hamamelidis folium et cortex aut ramunculus destillatum 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 - incture (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.
Harpagophyti radix Monograph Assessment report	Pain and inflammation	For relief of minor articular pain.	Herbal substance: Cut dried tuberous secondary root Herbal preparations -Powdered herbal substance -Comminuted herbal substance -Liquid extract (1:1; 30% (V/V) ethanol) -Soft extract (2.5-4.0:1; 70% (V/V) ethanol) -Dry extract (1.5-2.5:1; water) -Dry extract (5-10:1; water) -Dry extract (2.6-4:1; 30% (V/V) ethanol) -Dry extract (1.5-2.1:1; 40% (V/V) ethanol) -Dry extract (3-5:1; 60% (V/V) ethanol) -Dry extract (3-6:1; 80% (V/V) ethanol) -Dry extract (6-12:1; 90% (V/V) ethanol)	Solid or liquid dosage forms or as herbal tea for oral use.	Adults	The use is not recommended due to lack of adequate experience.
Harpagophyti radix Monograph Assessment report	Gastro-intestinal disorders	For the relief of mild digestive disorders such as bloating and flatulence.	Herbal substance Cut dried tuberous secondary root Herbal preparations -Powdered herbal substance -Comminuted herbal substance -Liquid extract (1:1; 30% (V/V) ethanol) -Soft extract (2.5-4.0:1; 70% (V/V) ethanol) -Dry extract (1.5-2.5:1; water) -Dry extract (5-10:1; water) -Dry extract (2.6-4:1; 30% (V/V) ethanol) -Dry extract (1.5-2.1:1; 40% (V/V) ethanol) -Dry extract (3-5:1; 60% (V/V) ethanol) -Dry extract (3-6:1; 80% (V/V) ethanol) -Dry extract (6-12:1; 90% (V/V) ethanol)	Solid or liquid dosage forms or as herbal tea 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
Harpagophyti radix Monograph Assessment report	Loss of appetite	Used in loss of appetite.	Herbal substance Cut dried tuberous secondary root Herbal preparations -Powdered herbal substance -Comminuted herbal substance -Liquid extract (1:1; 30% (V/V) ethanol) -Soft extract (2.5-4.0:1; 70% (V/V) ethanol) -Dry extract (1.5-2.5:1; water) -Dry extract (5-10:1; water) -Dry extract (2.6-4:1; 30% (V/V) ethanol) -Dry extract (1.5-2.1:1; 40% (V/V) ethanol) -Dry extract (3-5:1; 60% (V/V) ethanol) -Dry extract (3-6:1; 80% (V/V) ethanol) -Dry extract (6-12:1; 90% (V/V) ethanol)	Solid or liquid dosage forms or as herbal tea for oral use.	Adults	The use is not recommended due to lack of adequate experience.
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 in children and adolescents under 18 years of age has not been established 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 in children and adolescents under 18 years of age has not been established due to lack of adequate data.
Hippocastani semen Monograph Assessment report	Circulatory disorders	Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances.	Herbal preparations -Dry extract (ethanol 25-50% V/V) in a strength corresponding to ca 1% aescin in an ointment/gel base -Tincture (1:5; extraction solvent: 50% ethanol (V/V)), 20% in an ointment/gel base	Herbal preparations in semi-solid dosage forms for cutaneous use.	Adults	The use is not relevant because the indication does not occur in children and adolescents.
Hippocastani semen Monograph Assessment report	Circulatory disorders	For relief of signs of bruises, such as local oedema and haematoma.	Herbal preparations -Dry extract (ethanol 25-50% V/V) in a strength corresponding to ca 1% aescin in an ointment/gel base -Tincture (1:5; extraction solvent: 50% ethanol (V/V)), 20% in an ointment/gel base	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
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) - (C) Liquid extract (DER 1: 13), extraction solvent maize oil or other suitable vegetable oil - (D) Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45-50% (V/V) - (E) Tincture (Ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 50% (V/V) - (F) Liquid extract (DER 1:2), extraction solvent ethanol 50% (V/V) - (G) Liquid extract (DER 1:5-7), extraction solvent ethanol 50% (V/V) - (H) Expressed juice from the fresh herb (DER 1.1-2.5:1) - (I) Comminuted herbal substance: For tea preparation - (J) Powdered herbal substance	Comminuted herbal substance as herbal tea for oral use. Herbal preparations A,J in solid dosage forms for oral use. Herbal preparations C, D, E, F, G, H in liquid dosage forms for oral use.	Adults	The use is not recommended due to lack of adequate data.
Hyperici herba 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 preparations - (B) Liquid extract (DER 1:4-20), extraction solvent vegetable oil - (I) Comminuted herbal substance - (D) Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45-50% (V/V) - (E) Tincture (Ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 50% (V/V)	Herbal preparations in liquid or semi-solid dosage forms for cutaneous use.	Adolescents Adults	The use is not recommended due to lack of adequate data.
Hyperici herba Monograph Assessment report	Gastro-intestinal disorders	For the symptomatic relief of mild gastrointestinal discomfort.	Herbal preparations Comminuted herbal substance: For tea preparation	Comminuted herbal substance as herbal tea for oral use.	Adults	The use is not recommended due to lack of adequate data.
Juglandis folium 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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
Juglandis folium 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.
Juniperi aetheroleum 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.
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.
Juniperi aetheroleum 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.
Juniperi pseudo-fructus 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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
Juniperi pseudo-fructus 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.
Lavandulae aetheroleum 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.
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.

	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 cardiaca 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 cardiaca 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.
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)	a: Adolescents Adults d: Adults 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 a) Comminuted herbal substance	Comminuted herbal substance as herbal tea for oral use.	a: Adults	a: 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
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 -Powdered 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.
Lupuli flos Monograph Assessment report	Sleep disorders and temporary insomnia	Used to aid sleep.	Herbal preparations -Comminuted herbal substance -Powdered 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.
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.	Prep. a Infants from 6 months Children Adolescents Adults Prep. e,g,k,l Children older than 6 years Adolescents Adults Prep. 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)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 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.	Prep. h Children older than 6 years Adolescents Adults Prep. 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)3 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.	Prep.a, h Children older than 6 years Adolescents Adults Prep. 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)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 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/Vj)Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3)	Herbal preparations in semi-solid dosage forms for cutaneous use. Herbal preparations in liquid dosage forms for use as bath additives.	Prep m,o Infants from 4 weeks Children Adolescents Adults Prep.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)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)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/mg)Liquid extract (DER 1:1.7-2.6), extraction solvent ethanol 48% V/V 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/Vj)Liquid extract (DER 1:4.1-4.6), extraction solvent ethanol 55% V/V : Poloxamer 188 (993:3)	Herbal preparations in semi-solid dosage forms for cutaneous use. Herbal preparations in liquid dosage forms for use as bath additives.	Prep m,o Infants from 4 weeks Children Adolescents Adults Prep.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
Melaleucaea 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.
Melaleucaea 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.
Melaleucaea alternifoliae aetheroleum Monograph Assessment report	Skin disorders & minor wounds	For the relief of itching and irritation in cases of mild athlete`s foot.	Herbal preparations 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.
Melaleucaea alternifoliae aetheroleum Monograph Assessment report	Mouth and throat disorders	For symptomatic treatment of minor inflammation of the oral mucosa	Herbal preparations 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 preparations: -Comminuted herbal substance for tea preparation -Powdered herbal substance -Dry extracts (3-5:1), water -Liquid extracts (1:1), ethanol 30% (V/V) -Dry extracts (5-7:1), ethanol 50% (V/V) -Dry extracts (4-8:1), ethanol 25% m/m -Dry extracts (4-8:1), methanol 50% (V/V) -Dry extracts (4-8:1), ethanol 35% (V/V) -Dry extracts (6-9:1), ethanol 90% (V/V) -Dry extracts (7-9:1), methanol 30% (V/V)	Liquid dosage forms for oral use.	Adults	The use is not relevant because the indication does not occur in children and adolescents.
Meliloti herba Monograph Assessment report	Circulatory disorders	Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances.	Herbal preparations: Comminuted herbal substance for decoction	Semi-solid dosage forms for cutaneous use.	Adults	The use is not relevant because the indication does not occur in children and adolescents.
Meliloti herba Monograph Assessment report	Pain and inflammation	For symptomatic treatment of bruises and sprains.	Herbal preparations Comminuted herbal substance for decoction	Semi-solid dosage forms for cutaneous use.	Adults	The use is not recommended due to lack of adequate data.
Meliloti herba Monograph Assessment report	Pain and inflammation	For symptomatic treatment of insect bites.	Herbal preparations -Comminuted herbal substance for decoction -Emplastrum Meliloti: for single use	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.

	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	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 solvent1:5), 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	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 solvent1:5), 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 obtained by steam distillation from the fresh aerial parts of the flowering plant	Liquid or semi-solid preparations For cutaneous and transdermal use.	Children older than 4 years Adolescents Adults	Children younger than 2 years: the use is contraindicated. Children between 2-4 years: the use is not recommended due to lack of adequate experience.
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 obtained by steam distillation from the fresh aerial parts of the flowering plant	Liquid or semi-solid preparations For cutaneous and transdermal use.	Children older than 4 years Adolescents Adults	Children younger than 2 years: the use is contraindicated. Children between 2-4 years: 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
Menthae piperitae aetheroleum Monograph Assessment report	Cough and cold	For the relief of symptoms in coughs and colds.	Herbal preparation Essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant	Liquid or semi-solid preparations for cutaneous and transdermal use.	Children older than 4 years Adolescents Adults	Children younger than 2 years: the use is contraindicated. Children older than 2 years: the use is not recommended due to lack of adequate experience.
Menthae piperitae aetheroleum Monograph Assessment report	Cough and cold	For the relief of symptoms in coughs and colds.	Herbal preparation Essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant	Liquid or semi-solid preparations for inhalation.	Adolescents Adults	Children younger than 2 years: the use is contraindicated. Children older than 2 years: The use is not recommended due to lack of adequate experience.
Menthae piperitae aetheroleum Monograph Assessment report	Cough and cold	For the relief of symptoms in coughs and colds.	Herbal preparation Essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant	Liquid or semi-solid preparations for oromucosal use.	Children older than 4 years Adolescents Adults	Children younger than 2 years: the use is contraindicated. Children older than 2 years: the use is not recommended due to lack of adequate experience.
Menthae piperitae folium Monograph Assessment report	Gastro-intestinal disorders	For the symptomatic relief of digestive disorders such as dyspepsia and flatulence.	Herbal substance Mentha x piperita L., folium (dried peppermint leaf) Herbal preparations -Comminuted herbal substance for tea preparation -Tincture (1:5; ethanol 45% (V/V)) -Tincture (1:5; ethanol 70% (V/V))	Herbal substance for infusion or other herbal preparation in liquid or solid dosage forms for oral use.	Children older than 4 years Adolescents Adults	Children younger than 2 years: the use is contraindicated. Children older than 2 years: the use is not recommended due to lack of adequate experience.
Millefolii flos Monograph Assessment report	Loss of appetite	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 -Comminuted herbal substance -Expressed juice from fresh herb (DER: 1:0.6-0.9) -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) -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	The use is not recommended due to lack of adequate data.
Millefolii herba Monograph Assessment report	Gastro-intestinal disorders	Symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.	Herbal preparations -Comminuted herbal substance -Expressed juice from fresh herb (DER: 1:0.6-0.9) -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) -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	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	Skin disorders and minor wounds	Used for treatment of small superficial wounds.	Herbal preparations -Comminuted herbal substance -Expressed juice from fresh herb (DER: 1:0.6-0.9) -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) -Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 31.5% (V/V)	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	Use for symptomatic treatment of minor spasm associated with menstrual periods.	Herbal preparations -Comminuted herbal substance -Expressed juice from fresh herb (DER: 1:0.6-0.9) -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) -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	Prepubertal children: the indication is not relevant to this age category.
Myrrha Monograph Assessment report	Skin disorders and minor wounds	For treatment of minor ulcers and inflammation in the mouth (stomatitis and gingivitis).	Herbal preparations 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.
Myrrha Monograph Assessment report	Skin disorders and minor wounds	For treatment of minor wounds and small boils (furuncles).	Herbal preparations Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 90% V/V))	Herbal preparation in liquid dosage forms for r cutaneous use.	Adolescents Adults	The use is not recommended due to lack of adequate data.
Myrrha Monograph Assessment report	Mouth and throat disorders	For treatment of minor ulcers and inflammation in the mouth (stomatitis and gingivitis).	Herbal preparations: Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 90% (V/V))	Herbal preparation in liquid dosage forms for oromucosal or cutaneous use.	Adolescents , adults and elderly	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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
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.
Oenotherae biennis oleum Monograph Assessment report	Skin disorders and minor wounds	For the symptomatic relief of itching in acute and chronic dry skin conditions.	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	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 herbal substance (dried leaves) -Powdered herbal substance (dried leaves)	Herbal substance and 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
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.
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.
Orthosiphon is 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 substance: Dried, fragmented leaf Herbal preparations -Powder -Liquid extract (1:1, ethanol 25% m/m) -Dry extract (5-7:1, water) -Dry extract (4-5:1, ethanol 25% m/m) -Dry extract (5-7:1, ethanol 30% (V/V)) -Dry extract (5-7:1, ethanol 60% (V/V)) -Dry extract (8-12: 1 ethanol 60% (V/V)) -Dry extract (7-8:1, ethanol 70% (V/V))	Solid or liquid dosage forms or as herbal tea 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
Panax 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: k) Powdered herbal substance l) 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	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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
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
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 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.
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.
Plantaginis lanceolatae folium 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. Oralmucosal use: 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 preparations 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 preparations 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.
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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
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.
Rhodiolae 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.
Rhodiolae 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 substance Ribes nigrum L. folium (blackcurrant leaf) Herbal preparations -Comminuted herbal substance -Dry extract (DER 7:1), extraction solvent water: dry extract 7:1, water)	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
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 substance Ribes nigrum L. folium (blackcurrant leaf) Herbal preparations Dry extract (DER 7:1), extraction solvent water: dry extract (7:1, water)	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.
Rosae flos Monograph Assessment report	Mouth and throat disorders	Used for mild inflammations of the oral and pharyngeal mucosa.	Herbal substance Dried petals Herbal preparations 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 preparations 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 preparations 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 preparations 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.
Rosmarini folium Monograph Assessment report	Gastro-intestinal disorders	For symptomatic relief of dyspepsia and mild spasmodic 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.

	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	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 preparations: 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.
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 aculeati rhizoma Monograph Assessment report	Circulatory disorders	Used to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances.	Herbal preparations -Powdered root -Dry extract (2.5-6.5 : 1 ; water) -Dry extract (5-8.5 : 1 ; 80% (V/V) ethanol) -Dry extract (6-9 : 1 ; primary solvent 96% (V/V) ethanol followed by water) -Dry extract (15-20 : 1 ; 60% (V/V) methanol)	Solid dosage forms for oral use.	Adults	The use is not relevant because the indication does not occur in 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
Rusci aculeati rhizoma Monograph Assessment report	Circulatory disorders	For symptomatic relief of itching and burning associated with haemorrhoids.	Herbal preparations -Dried powdered root -Dry extract (2.5-6.5 : 1 ; water) -Dry extract (5-8.5 : 1 ; 80% (V/V) ethanol) -Dry extract (6-9 : 1 ; primary solvent 96% (V/V) ethanol followed by water) -Dry extract (15-20 : 1 ; 60% (V/V) methanol)	Solid dosage forms for oral use.	Adults	The use is not recommended due to lack of adequate data.
Sabalisserrulatae fructus 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 doctor.	Herbal preparation Soft extract (DER 7.5-14.3:1), extraction solvent: ethanol 90% to 96 % m/m	Herbal preparations in solid dosage form for oral use.	Adults	The use is not relevant because the indication does not occur in children and adolescents.
Saliciscortex Monograph Assessment report	Pain and inflammation	Used for minor articular pain.	Herbal preparations -Dry aqueous extracts (16-20:1, 8-16:1) -Dry aqueous extracts (16-23:1) -Liquid extract (1:1), extraction solvent ethanol 25% (V/V) -Tincture (1:5), extraction solvent ethanol 25% (V/V) -Comminuted herbal substance -Powdered herbal substance	Solid or liquid dosage form, or as herbal tea for oral use.	Adults	The use is not recommended because medical advice should be sought.
Saliciscortex Monograph Assessment report	Pain and inflammation	Used for headache.	Herbal preparations -Dry aqueous extracts (16-20:1, 8-16:1) -Dry aqueous extracts (16-23:1) -Liquid extract (1:1), extraction solvent ethanol 25% (V/V) -Tincture (1:5), extraction solvent ethanol 25% (V/V) -Comminuted herbal substance -Powdered herbal substance	Solid or liquid dosage form, or as herbal tea for oral use.	Adults	The use is not recommended because medical advice should be sought.
Saliciscortex Monograph Assessment report	Cough and cold	Used for fever associated with common cold.	Herbal preparations -Dry aqueous extracts (16-20:1, 8-16:1) -Dry aqueous extracts (16-23:1) -Liquid extract (1:1), extraction solvent ethanol 25% (V/V) -Tincture (1:5), extraction solvent ethanol 25% (V/V) -Comminuted herbal substance -Powdered herbal substance	Solid or liquid dosage form, or as herbal tea for oral use.	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
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: for tea preparation -Dry extract (4-7:1), extraction solvent: water -Liquid extract (1:3.5-5), extraction solvent: ethanol 31.5% (V/V) -Liquid extract (1:7.2), extraction solvent: liquor wine : ethanol 96% (V/V) (38.25:61.75 m/m) -Tincture (1:10), extraction solvent: ethanol 70% (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 and because medical advice should be sought.
Salviae officinalis folium Monograph Assessment report	Skin disorders and minor wounds	For relief of excessive sweating.	Herbal preparations -Comminuted herbal substance: for tea preparation -Liquid extract (1:3.5-5), extraction solvent: ethanol 31.5% (V/V) -Liquid extract (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 and because medical advice should be sought.
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 preparation of an infusion) for cutaneous use.	Adults	The use is not recommended due to lack of adequate data and because medical advice should be sought.
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 (1:1), extraction solvent ethanol 70% (V/V) -Liquid extract (1:3.5-5), extraction solvent: ethanol 31.5% (V/V) -Liquid extract (1:7.2), extraction solvent: liquor wine: ethanol 96% (V/V) (38.25:61.75 m/m) -Tincture (1:10), extraction solvent: ethanol 70% (V/V)	Comminuted herbal substance (for preparation of an infusion) for oromucosal use. Liquid or semi-solid preparations for oromucosal use.	Adults	The use is not recommended due to lack of adequate data and because medical advice should be sought.
Sambuci flos Monograph Assessment report	Cough and cold	For the relief of early symptoms of common cold.	Herbal substance Dried flower Herbal preparations -Liquid extract, DER 1:1, extraction solvent: 25% V/V ethanol -Tincture, DER 1:5, extraction solvent: 25% V/V ethanol	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
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.	Oralmucosal use Children between 6 and 11 years of age Adolescents Adults Oral use Children between 3 and 11 years of age Adolescents Adults	Oralmucosal use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form) Oral use The 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.
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.
Symphyti radix Monograph Assessment report	Pain and inflammation	For the symptomatic relief of minor sprains and bruises	Herbal preparations: Liquid extract prepared by extraction with ethanol 65% (V/V) followed by partial evaporation and adjustment to a DER 2:1	Herbal preparations in semi-solid dosage forms for cutaneous use.	Adults	The use is not recommended due to lack of adequate data.
Tanacetii 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 preparations Powdered herbal substance	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
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 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 -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 -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	Urinary tract and gynecology 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 root with herb, comminuted	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.
Thymi aetheroleum Monograph Assessment report	Cough and cold	Used as an expectorant in cough associated with cold.	Herbal preparation Essential oil	Liquid dosage forms for oral use	Children older than 4 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
Thymi aetheroleum Monograph Assessment report	Cough and cold	For the relief of symptoms in coughs and colds.	Herbal preparation Essential oil	Solid or liquid dosage forms for cutaneous use.	Use as bath additive: Children older than 3 years Adolescents Adults 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.
Thymi herba Monograph Assessment report	Cough and cold	Used as an expectorant in cough associated with cold.	Herbal preparations: -(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) -(g) Liquid extract from fresh herb (1:1.5-2.4), extraction solvent water (often referred as "expressed juice") -Liquid extract (1:1), extraction solvent ethanol 24% (V/V) -Liquid extract (1:1.16), extraction solvent glycerol 85% (m/m): ethanol 25% (m/m)(0.1:2) -Tincture (1:10), extraction solvent ethanol 70% (V/V) -Tincture (1:5), extraction solvent ethanol 70% (V/V) -Soft extract (5-8:1), extraction solvent ethanol 25% (V/V) or methanol 25% -Dry extract (6-10:1), extraction solvent ethanol 70% (V/V) -Dry extract (1.6-2.4:1), extraction solvent ethanol 96% (V/V) -Liquid extract (1-4.5), extraction solvent ammonia solution 10% (m/m) : glycerol 85% (m/m) : ethanol 96% (V/V) : water (1.2:25:112:113) -Dry extract (7-13:1), extraction solvent water -Comminuted herbal substance	Comminuted herbal substance as herbal tea for oral use or Liquid or solid dosage forms for oral use.	Herbal preparations s c and g : Children older than 4 years Adolescents Adults Other preparations: Adolescents Cduits	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.
Tiliae flos Monograph Assessment report	Cough and cold	For the relief of symptoms of common cold.	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.	Children between 4 and 12 years of age Adolescents Adults	The use in children under 4 years of age has not been established due to lack of adequate data.
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.

	Therapeutic area	Indication	Herbal substances and/or preparations referred in the monograph	Dosage form and method of administration	Target population	Justification for limited use
Tormentilla e 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.
Tormentilla e 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.
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
Urticae herba Monograph Assessment report	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.
Urticae herba Monograph Assessment report	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.
Uvae ursi folium Monograph Assessment report	Urinary tract and genital disorders	Used for treatment of symptoms of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent urination, after serious conditions have been excluded by a medical doctor.	Herbal preparations -Comminuted herbal substance -Powdered herbal substance -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) -Dry extract (DER 2.5-4.5:1), extraction solvent water, containing 20-28% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry)	Herbal preparations in solid dosage forms or as herbal tea for oral use.	Female adults	The use is not recommended due to lack of adequate data.
Valerianae radix Monograph Assessment report	Sleep disorders and temporary insomnia	Used to aid sleep.	Herbal substance Dried valerian root Herbal preparations -Dry extracts prepared with water -Valerian tincture -Expressed juice from fresh root -Valerian root oil	Solid or liquid dosage forms for oral use.	Adolescents Adults	The use is not recommended due to lack of adequate data.
Valerianae radix Monograph Assessment report	Mental stress and mood disorders	Relief of mild symptoms of mental stress.	Herbal substance Dried valerian root Herbal preparations -Dry extracts prepared with water -Valerian tincture -Expressed juice from fresh root -Valerian root oil	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
Valerianae radix and Lupuli flos Monograph Assessment report	Sleep disorders and temporary insomnia	Used to aid sleep.	Herbal preparations used in fixed combinations of: -Liquid extract (DER 1:6.3) from a mixture of valerian root-hop strobiles (1:1), extraction solvent ethanol 40% (V/V) -Liquid extract from a mixture (1:1) of valerian root tincture (DER 1:10), extraction solvent ethanol 53% m/m and hop strobiles liquid extract (DER 1:2.2), extraction solvent ethanol 53% m/m -Dry extracts of valerian root (DER 4-6:1), extraction solvent water and hop strobiles (DER 3-6:1), extraction solvent water -Dry extracts of valerian root (DER 5-7:1), extraction solvent methanol 45% m/m and hop strobiles (DER 5-7:1), extraction solvent water -Dry extracts of valerian root (DER 4-5:1), extraction solvent ethanol 60% (V/V) and hop strobiles (DER 5-9:1), extraction solvent water -Dry extracts of valerian root (DER 4-7:1), extraction solvent methanol 45% (V/V) and hop strobiles (DER 4-8:1), extraction solvent ethanol 40% (V/V) -Dry extracts of valerian root (DER 3-7:1), extraction solvent ethanol 70% (V/V) and hop strobiles (DER 4-8:1), extraction solvent ethanol 40% (V/V) -Dry extracts of valerian root (DER 6-7:1), extraction solvent ethanol 70% (V/V) and hop strobiles (DER 11-14:1), extraction solvent ethanol 96% (V/V) -Dry extracts of valerian root (DER 5-8:1), extraction solvent ethanol 85% (V/V) and hop strobiles (DER 9-11:1), extraction solvent ethanol 90% (V/V)	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
Valerianae radix and Lupuli flos Monograph Assessment report	Mental stress and mood disorders	For relief of mild symptoms of mental stress.	Herbal preparations used in fixed combinations of: -Liquid extract (DER 1:6.3) from a mixture of valerian root-hop strobiles (1:1), extraction solvent ethanol 40% (V/V) -Liquid extract from a mixture (1:1) of valerian root tincture (DER 1:10), extraction solvent ethanol 53% m/m and hop strobiles liquid extract (DER 1:2.2), extraction solvent ethanol 53% m/m -Dry extracts of valerian root (DER 4-6:1), extraction solvent water and hop strobiles (DER 3-6:1), extraction solvent water -Dry extracts of valerian root (DER 5-7:1), extraction solvent methanol 45% m/m and hop strobiles (DER 5-7:1), extraction solvent water -Dry extracts of valerian root (DER 4-5:1), extraction solvent ethanol 60% (V/V) and hop strobiles (DER 5-9:1), extraction solvent water - Dry extracts of valerian root (DER 4-7:1), extraction solvent methanol 45% (V/V) and hop strobiles (DER 4-8:1), extraction solvent ethanol 40% (V/V) -Dry extracts of valerian root (DER 3-7:1), extraction solvent ethanol 70% (V/V) and hop strobiles (DER 4-8:1), extraction solvent ethanol 40% (V/V) -Dry extracts of valerian root (DER 6-7:1), extraction solvent ethanol 70% (V/V) and hop strobiles (DER 11-14:1), extraction solvent ethanol 96% (V/V) -Dry extracts of valerian root (DER 5-8:1), extraction solvent ethanol 85% (V/V) and hop strobiles (DER 9-11:1), extraction solvent ethanol 90% (V/V)	Solid or liquid dosage forms for oral use.	Adolescents Adults	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.	Herbal substance Dried flowers, reduced to the corolla and the androecium Herbal preparations Comminuted herbal substance	Herbal tea for oral use.	Adolescents 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 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
Violae herba cum flore Monograph Assessment report	Skin disorders and minor wounds	For symptomatic treatment of mild seborrhoeic skin conditions.	Herbal preparations 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.
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 -Powdered herbal substance -Soft extract (DER 2.5-4: 1); extraction solvent water: base (10 g contain 282 mg soft extract)	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 use is not relevant because the indication does not occur in 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 -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 relief of itching and burning associated with haemorrhoids.	Herbal preparations -Comminuted herbal substance -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.
Zingiberis rhizoma Monograph Assessment report	Gastro-intestinal disorders	For the symptomatic relief of motion sickness.	Herbal preparations 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.

	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 symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence.	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.