



21 March 2022
EMA/HMPC/180400/2018
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Species digestivae* Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP) and Committee on Herbal Medicinal Products (HMPC)	September 2017 November 2017 March 2018 June 2018 2019 September 2020 November 2020 January 2021 March 2021 May 2021 July 2021
Adopted by HMPC for release for consultation	07 July 2021
End of consultation (deadline for comments)	31 October 2021
Re-discussion in HMPC	November 2021 January 2022 March 2022
Adoption by HMPC	30 March 2022

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; herbal tea combinations for use in gastrointestinal complaints; <i>Species digestivae</i>
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BG (bulgarski): Чай при стомашно-чревни оплаквания, комбинации	LT (lietuvių kalba): Virškinimą skatinantis ir gerinantis mišinys
CS (čeština): žaludeční čajová směs	LV (latviešu valoda): Tēja gremošanas veicināšanai / gremošanas sistēmai
DA (dansk): Fordøjelseste	MT (Malti): speċi diġestivi
DE (Deutsch): Verdauungstees	NL (Nederlands): Maag- en darmkruiden
EL (elliniká): Μίγματα φυτικών ειδών για εγχύματα/αφεψήματα με ευστόμαχη δράση	PL (polski):
EN (English): Herbal tea combinations for use in gastrointestinal complaints	PT (português): associações de substâncias vegetais para utilização em tisanas com acção digestiva / estomáquica
ES (español): combinaciones de sustancias vegetales para uso en tisana con acción digestiva / estomáquica	RO (română): ceai gastric
ET (eesti keel):	SK (slovenčina): žalúdková čajovina
FI (suomi): ruoansulatusvaivoissa perinteisesti käytetyt yhdistelmäteevalmisteet	SL (slovenščina): zdravilni čaji za prebavo / želodec
FR (français): espèces digestives / stomachiques	SV (svenska): örtteer vid matsmältningsbesvär / mag-tarmbesvär
HR (hrvatski): čajevi za probavu / želudac	IS (íslenska):
HU (magyar): Emésztést elősegítő teakeverék	NO (norsk):
IT (italiano): Specie composte per tisane digestive / stomachiche	

European Union herbal monograph on *Species digestivae*

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1, 2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p>Herbal tea combinations containing several herbal substances out of the following list:</p> <p><i>Achillea millefolium</i> L., herba, flos</p> <p><i>Aloysia citrodora</i> Paláu (syn. <i>Aloysia triphylla</i> (L'Hér.) Kuntze; <i>Verbena triphylla</i> L'Hér.; <i>Lippia citriodora</i> Kunth), folium (Verbenae citriodoraefolium)</p> <p><i>Althaea officinalis</i> L., radix</p> <p><i>Artemisia absinthium</i> L., herba</p> <p><i>Carum carvi</i> L., aetheroleum, fructus</p> <p><i>Centaurium erythraea</i> Rafn. s.l., herba</p> <p><i>Cinnamomum verum</i> J. S. Presl, (<i>Cinnamomum zeylanicum</i> Nees), cortex</p> <p><i>Curcuma xanthorrhiza</i> Roxb. (<i>C. xanthorrhiza</i> D. Dietrich), rhizoma</p> <p><i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Mill.) Batt. & Trab., fructus</p> <p><i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i>, fructus</p> <p><i>Fumaria officinalis</i> L., herba</p> <p><i>Gentiana lutea</i> L., radix</p> <p><i>Glycyrrhiza glabra</i> L.; <i>Glycyrrhiza inflata</i> Bat.; <i>Glycyrrhiza uralensis</i> Fisch., radix</p> <p><i>Hypericum perforatum</i> L., herba</p> <p><i>Marrubium vulgare</i> L., herba</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the respective monographs in the Ph. Eur.

Well-established use	Traditional use
	<p><i>Matricaria recutita</i> L., flos</p> <p><i>Melissa officinalis</i> L., folium</p> <p><i>Mentha x piperita</i> L., folium</p> <p><i>Menyanthes trifoliata</i> L., folium</p> <p><i>Peumus boldus</i> Molina, folium</p> <p><i>Pimpinella anisum</i> L., fructus</p> <p><i>Rosmarinus officinalis</i> L. folium</p> <p><i>Salvia officinalis</i> L., folium</p> <p><i>Taraxacum officinale</i> Weber ex Wigg., radix cum herba</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Combinations of the comminuted herbal substances (see combinations table below)</p>

	Absinthii herba	Aloysiae folium	Althaeae radix	Anisi fructus	Boldi folium	Carvi fructus	Centaurii herba	Cinnamomi cortex	Curcumae xanthorrhizae rhizoma	Foeniculi amari fructus	Foeniculi dulcis fructus	Fumariae herba	Gentianae radix	Hyperici herba	Liquiritiae radix	Marrubii herba	Matricariae flos	Melissae folium	Menthae piperitae herba	Menyanthidis folium	Millefolii herba/flos	Rosmarini herba	Salviae officinalis folium	Taraxaci radix cum herba	Range in combination (excl. excipients)
Absinthii herba							+	+					+					+	+		+				10-50%
Aloysiae folium			+	+													+		+			+			10%
Althaeae radix		+		+						+					+		+		+						10%
Anisi fructus		+	+			+	+			+							+	+			+	+			10-40%
Boldi folium												+				+	+		+	+		+		+	10-32%
Carvi fructus				+					+	+							+		+		+			+	10-40%
Centaurii herba	+							+		+			+	+			+		+		+	+		+	10-35%
Cinnamomi cortex	+						+						+												10%
Curcumae xanthorrhizae rhizoma						+													+		+			+	15-20%
Foeniculi amari fructus				+		+	+										+		+	+	+				14-40%
Foeniculi dulcis fructus			+				+							+	+		+		+						10-22%
Fumariae herba					+														+	+		+		+	13%
Gentianae radix	+						+	+			+				+		+				+			+	10-30%
Hyperici herba							+			+							+		+						10%
Liquiritiae radix			+							+							+		+		+		+		10-35%
Marrubii herba					+												+		+					+	25%
Matricariae flos		+	+			+	+			+								+	+	+	+	+			10-40%
Melissae folium	+			+						+							+				+				10-35%
Menthae piperitae herba	+	+	+	+	+	+	+		+	+		+		+	+	+	+	+		+	+	+	+	+	10-40%
Menyanthidis folium					+							+							+			+		+	11%
Millefolii herba/flos			+	+	+	+	+			+					+		+	+	+						10-50%

Rosmarini herba		+		+	+							+				+		+	+				+	10-16%	
Salviae officinalis folium														+		+		+							10%
Taraxaci radix cum herba					+		+						+					+	+			+			19-25%

A + indicates the evidence of traditional medicinal use of a certain combination.

Out of these documented combinations the combination partners for an application for a traditional herbal medicinal product may be chosen.

The number of active substances in an herbal tea combination is recommended to be limited to a maximum of 4. Further herbal substances may be added as excipients. Their number, amount and function should be justified.

The very right row indicates the traditional amount of the herbal substance in the combinations. The calculation is based on those combination partners only, which contribute to the plausibility of the traditional medicinal use. The amount in a traditional herbal medicinal product should be within this range. The sum of active ingredients should end up with 100%. Excipients are not considered in this range.

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substances as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for the symptomatic relief of mild dyspeptic / gastrointestinal disorders including bloating and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration ³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and Elderly</i></p> <p><i>Combinations containing (among other active ingredients) Absinthii herba, Anisi fructus, Boldi folium, Carvi fructus, Centaurii herba, Cinnamomi cortex, Curcumae xanthorrhizae rhizoma, Fumariae herba, Gentianae radix, Hyperici herba, Liquiritiae radix, Melissa folium, Menyanthidis trifoliatae folium, Millefolii herba, Rosmarini herba, Salviae officinalis folium or Taraxaci radix cum herba:</i></p> <p>Herbal tea: 1.5-2 g of the herbal tea combination in 150 ml of boiling water as an herbal infusion 3 times daily.</p> <p><i>For combinations with Anisi fructus: see section 6 for content of estragole.</i></p>

³ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	<p><i>Adolescents, Adults and Elderly</i></p> <p><i>Combinations containing Verbenae citriodoraefolium, Althaeae radix, Foeniculi amari fructus, Marrubii herba, Matricariae flos or Menthae piperitae herba:</i></p> <p>Herbal tea: 1.5-2 g of the herbal tea combination in 150 ml of boiling water as an herbal infusion 1-2 times daily.</p> <p><i>For combinations with Foeniculi amari fructus and/or Foeniculi dulci fructus: see section 6 for content of estragole.</i></p> <p><i>Depending on the herbal substances included:</i></p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><i>or</i></p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing Foeniculi amari fructus and/or Foeniculi dulci fructus and/or Anisi fructus:</i></p> <p>Not to be used for more than 2 weeks.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p><i>All combinations:</i></p> <p>Hypersensitivity to the active substances.</p> <p><i>Combinations containing Absinthii herba, Matricariae flos, Millefolii herba or Taraxaci radix cum herba:</i></p> <p>Additionally: Hypersensitivity to other plants of</p>

Well-established use	Traditional use
	<p>the Asteraceae family.</p> <p><i>Combinations containing Anisi fructus, Carvi fructus Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p><i>Additionally:</i> Hypersensitivity to other plants of the Apiaceae family (fennel, anise, celery, coriander and dill).</p> <p><i>Combinations containing Verbenae citriodoraе folium:</i></p> <p><i>Additionally:</i> Hypersensitivity to other plants of the Verbenaceae family.</p> <p><i>Combinations containing Marrubii herba:</i></p> <p><i>Additionally:</i> Hypersensitivity to other plants of the Lamiaceae family.</p> <p><i>Combinations containing Menyanthidis trifoliatae folium:</i></p> <p><i>Additionally:</i> Active gastric or duodenal ulcer.</p> <p><i>Combinations containing Absinthii herba, Boldi folium, Fumariae herba, Marrubii herba, Rosmarini herba or Taraxaci radix cum herba:</i></p> <p><i>Additionally:</i> Obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary disorders.</p> <p><i>Combinations containing Centaurii herba; Gentianaе radix or Taraxaci radix cum herba:</i></p> <p><i>Additionally:</i> Peptic ulcer.</p> <p><i>Combinations containing Anisi fructus, Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p><i>Additionally:</i> Hypersensitivity to anethole.</p> <p><i>Combinations containing Carvi fructus:</i></p> <p><i>Additionally:</i> Hypersensitivity to mugwort or to birch.</p> <p><i>Combinations containing Cinnamomi cortex:</i></p> <p><i>Additionally:</i> Hypersensitivity to Peru balsam.</p> <p><i>Combinations containing Menthae piperitae herba:</i></p> <p><i>Additionally:</i> Hypersensitivity to menthol.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<i>Depending on the herbal substances included:</i>

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p><i>or</i></p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p><i>Combinations containing Anisi fructus, Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p>The use in children under 12 years of age has not been established due to lack of adequate data for safety assessment (see section 5.3 regarding preclinical safety related to the content of estragole).</p> <p><i>Combinations containing Absinthii herba, Carvi fructus, Curcumae xanthorrhizae rhizoma, Marrubii herba or Menthae piperitae herba:</i></p> <p>Gallstones, liver disease, cholangitis and any other biliary disorders.</p> <p><i>Combinations containing Althaeae radix:</i></p> <p>Not to be taken ½ to 1 h before or after intake of other medicinal products.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>Hypertension, cardiac rhythm disorders, kidney diseases, liver or cardiovascular disorders or hypokalaemia. Concomitant use with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance is not recommended.</p> <p><i>Combinations containing Marrubii herba:</i></p> <p>Active peptic ulcer.</p> <p><i>Combinations containing Menthae piperitae herba:</i></p> <p>Patients with gastro-oesophageal reflux (heartburn).</p> <p><i>Combinations containing Taraxaci radix cum herba:</i></p> <p>Patients with renal failure and/or diabetes, and/or heart failure because of possible risks</p>

Well-established use	Traditional use
	<p>due to hyperkalaemia.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	<p><i>All combinations except those containing Liquiritiae radix and/or Matricariae flos:</i></p> <p>None reported.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>Not to use concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance.</p> <p><i>Combinations containing Matricariae flos:</i></p> <p>For patients after renal transplantation taking high doses for longer periods (about 2 months) interactions based on effects on CYP450 have been reported.</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p><i>All combinations (except for those containing Anisi fructus, Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p> <p><i>Combinations containing Anisi fructus, Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p>Safety during pregnancy and lactation has not been established (see section 5.3 regarding preclinical safety related to the content of estragole).</p> <p>In the absence of sufficient data, the use during</p>

Well-established use	Traditional use
	<p>pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	<p><i>All combinations except for those containing <i>Melissae folium</i>:</i></p> <p>No studies on the effect on the ability to drive and use machines have been performed.</p> <p><i>Combinations containing <i>Melissae folium</i>:</i></p> <p>May impair ability to drive and use machines. Affected patients should not drive or operate machinery.</p>

4.8. Undesirable effects

Well-established use	Traditional use
	<p><i>Combinations containing <i>Absinthii herba</i>, <i>Althaeae radix</i>, <i>Carvi fructus</i>, <i>Centaurii herba</i>, <i>Cinnamomi cortex</i>, <i>Fumariae herba</i>, <i>Liquiritiae radix</i>, <i>Melissae folium</i>, <i>Marrubii herba</i> or <i>Salviae officinalis folium</i>:</i></p> <p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing <i>Anisi fructus</i>:</i></p> <p>Allergic reactions to aniseed affecting the skin or the respiratory system have been reported. The frequency is not known.</p> <p><i>Combinations containing <i>Boldi folium</i>:</i></p> <p>Hypersensitivity (anaphylaxis) has been reported.</p> <p>The frequency is not known</p> <p><i>Combinations containing <i>Foeniculi fructus</i> or <i>Rosmarini herba</i>:</i></p> <p>Allergic reactions affecting the skin, or the respiratory system may occur. The frequency is not known.</p> <p><i>Combinations containing <i>Curcumae</i></i></p>

Well-established use	Traditional use
	<p><i>xanthorrhizae rhizoma:</i></p> <p>Mild gastrointestinal symptoms such as dry mouth, flatulence and gastric irritation may occur. The frequency is not known.</p> <p><i>Combinations containing Gentianae radix:</i></p> <p>Gastrointestinal disorders have been observed. The frequency was uncommon.</p> <p>In rare cases, tachycardia and pruritus have been reported.</p> <p>Headache may occur. The frequency is not known.</p> <p><i>Combinations containing Hyperici herba:</i></p> <p>Gastrointestinal disorders, allergic skin reactions, fatigue and restlessness may occur. The frequency is not known.</p> <p>Fair-skinned individuals may react with intensified sunburn-like symptoms under intense sunlight.</p> <p><i>Combinations containing Matricariae flos:</i></p> <p>Hypersensitivity reactions including severe allergic reaction (dyspnoea, Quincke's disease, vascular collapse, anaphylactic shock) following mucosal contact with liquid chamomile preparations have been reported. The frequency is not known.</p> <p><i>Combinations containing Menthae piperitae herba:</i></p> <p>The gastro-oesophageal reflux may worsen, and heartburn may increase. The frequency is not known.</p> <p><i>Combinations containing Millefolii herba:</i></p> <p>Hypersensitivity reactions of the skin have been reported. The frequency is not known.</p> <p><i>Combinations containing Taraxaci radix cum herba:</i></p> <p>Epigastric pain and hyperacidity may occur. The frequency is not known.</p> <p>Allergic reactions may occur. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

Well-established use	Traditional use
	<p><i>All combinations except those containing Centaurii herba and/or Liquiritiae radix:</i></p> <p>No case of overdose has been reported.</p> <p>Combinations containing Centaurii herba:</p> <p>Stomach disturbances and nausea have been reported.</p> <p>Combinations containing Liquiritiae radix:</p> <p>Water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy.</p>

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data⁴

Well-established use	Traditional use
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.</p> <p><i>Combinations containing Absinthii herba:</i></p> <p>Thujone is reported to be neurotoxic and chemotypes with low content of thujone should be preferred.</p> <p>Tests on reproductive toxicity have been performed with a dry ethanolic extract of</p>

⁴ Where herbal preparations from Anisi fructus, Foeniculi dulce fructus or Foeniculi amara fructus are used, the total exposure to estragole must be considered from a safety standpoint.

Well-established use	Traditional use
	<p>Absinthii herba administered orally to pregnant rats. Results showed reduced sites of implantations and a reduced rate of born pups. Thujone is known for its uterus stimulating activity.</p> <p><i>Combinations containing Anisi fructus, Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p>Several studies have shown the carcinogenic effects of estragole and some of its metabolites in mice (mainly malignant liver tumours) and displayed suggestive but indirect evidence of carcinogenicity in rats. Estragole is considered a genotoxic carcinogen in rodents.</p> <p>Results from non-clinical studies showed a weak mutagenic potential of anethole. Anethole and its metabolites are unlikely to be genotoxic <i>in vivo</i>.</p> <p><i>Combinations containing Boldi folium:</i></p> <p>Tests on genotoxicity and carcinogenicity have not been performed.</p> <p><i>Combinations containing Gentianae radix:</i></p> <p>For some xanthenes which are among the constituents of <i>Gentiana lutea</i>, positive results were found in the AMES test (pre-incubation method).</p> <p>Assessment of preclinical safety requires further studies towards these effects.</p> <p><i>Combinations containing Hyperici herba:</i></p> <p>Studies on acute toxicity and repeated dose toxicity did not show signs of toxic effects.</p> <p>Tests on reproductive toxicity revealed equivocal results.</p> <p>Tests on genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	<p><i>Combinations containing Absinthii herba or Salviae officinalis folium:</i></p>

Well-established use	Traditional use
	<p>The amount of thujone has to be specified in the given product. The daily exposure has to be below 6.0 mg.</p> <p><i>Combinations containing Boldi folium:</i></p> <p>The levels of ascaridole in herbal preparations and herbal medicinal products should be determined.</p> <p><i>Combinations containing Hyperici herba:</i></p> <p>The amount of hyperforin has to be specified in herbal preparation for oral use. The daily intake of hyperforin has to be below 1 mg.</p> <p><i>Combinations containing Anisi fructus, Foeniculi amari fructus or Foeniculi dulci fructus:</i></p> <p>Because of the generally accepted evidence of genotoxic carcinogenicity, exposure to estragole should be kept as low as practically achievable.</p> <p>The amount of estragole has to be specified in herbal preparation for oral use.</p> <p>For further details see 'Public statement on the use of herbal medicinal products containing estragole' (EMA/HMPC/137212/2005 Rev. 1).</p>

7. Date of compilation/last revision

30 March 2022