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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Species pectorales* Draft

<b>Initial assessment</b>	
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<p>BG (bulgarski): Чаеви смеси за употреба при кашлица и настинки</p> <p>CS (čeština): Čajová směs pro použití při onemocnění horních cest dýchacích a kašli</p> <p>DA (dansk): Urteteer ved hoste og forkølels</p> <p>DE (Deutsch): Teemischungen zur Anwendung bei Husten und Erkältungen(DE)/Brusttee(AT)</p> <p>EL (elliniká): Μείγματα φυτικών ειδών για έγχυμα/αφέψημα έναντι βήχα και κρυολογήματος</p> <p>EN (English): Herbal tea combinations for use in cough and cold</p> <p>ES (español):</p> <p>ET (eesti keel):</p> <p>FI (suomi): yskään ja vilustumiseen perinteisesti käytetyt yhdistelmäteevalmisteet</p> <p>FR (français): espèces pectorales</p> <p>HR (hrvatski): čajevi za kašalj i prehladu</p> <p>HU (magyar): köhögés elleni teakeverék</p> <p>IT (italiano): Specie composte per tisane ad azione lenitiva delle vie respiratorie superiori</p>	<p>LT (lietuvių kalba): Mišinys skirtas kosuliui ir peršalimui</p> <p>LV (latviešu valoda): Tēja pret klepu un saaukstēšanos</p> <p>MT (Malti): Pjanti għall-użu tal-kundizzjonijiet tas-sider (sistema respiratorja)ta' riġ</p> <p>NL (Nederlands): pectorale kruiden</p> <p>PL (polski): mieszanki ziołowe wykrztuśne</p> <p>PT (português): associações de substâncias vegetais para utilização em tisanas para a tosse e constipações</p> <p>RO (română):</p> <p>SK (slovenčina): prsná čajovina</p> <p>SL (slovenščina): zdravilni čaji za kašelj in prehlad</p> <p>SV (svenska): örtteer vid hosta och förkylning</p> <p>IS (íslenska):</p> <p>NO (norsk): urteteer ved hoste og forkjølelse</p>
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# European Union herbal monograph on *Species pectorales*

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1, 2</sup>

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>Althaea officinalis</i> L., radix <i>Cetraria islandica</i> (L.) Acharius s.l., thallus <i>Filipendula ulmaria</i> (L.) Maxim, flos <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i>, fructus <i>Glycyrrhiza glabra</i> L.; <i>Glycyrrhiza inflata</i> Bat.; <i>Glycyrrhiza uralensis</i> Fisch., radix <i>Plantago lanceolata</i> L., folium <i>Pimpinella anisum</i> L., fructus <i>Polygonum aviculare</i> L., herba <i>Primula veris</i> L.; <i>Primula elatior</i> (L.) Hill, flos <i>Salix</i> [various species including <i>S. purpurea</i> L.; <i>S. daphnoides</i> Vill.; <i>S. fragilis</i> L.], cortex <i>Sambucus nigra</i> L., flos <i>Thymus vulgaris</i> L.; <i>Thymus zygis</i> L., herba <i>Tilia cordata</i> Miller; <i>Tilia platyphyllos</i> Scop.; <i>Tilia x vulgaris</i> Heyne, flos <i>Verbascum thapsus</i> L.; <i>V. densiflorum</i> Bertol. (<i>V. thapsiforme</i> Schrad); <i>V. phlomoides</i> L., flos</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>

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

<sup>2</sup> The material complies with the Ph. Eur. monograph

	Althaea radix	Anisi fructus	Filipendula ulmaria flos	Foeniculi amari fructus	Lichen islandicus	Liquiritiae radix	Plantaginis folium	Polygoni avicularis herba	Primulae flos	Salicis cortex	Sambuci flos	Thymi herba	Tiliae flos	Verbasci flos	RANGE
Althaea radix		+		+	+	+	+	+			+	+		+	5-25%
Anisi fructus	+					+						+	+		10-40%
Filipendula ulmaria flos											+		+		20-30%
Foeniculi amari fructus	+				+	+	+	+	+		+	+	+	+	5-25%
Lichen islandicus	+			+		+	+	+	+			+	+	+	11.25-15%
Liquiritiae radix	+	+		+	+		+	+			+	+		+	5-35%
Plantaginis folium	+			+	+	+		+			+	+		+	5-40%
Polygoni avicularis herba	+			+	+	+	+		+		+	+	+	+	10-15%
Primulae flos				+	+			+				+	+	+	6.25%
Salicis cortex											+		+		20-60%
Sambuci flos	+		+			+	+	+		+		+	+		5-50%
Thymi herba	+	+		+	+	+	+	+	+	+	+		+	+	10-40%
Tiliae flos		+	+	+	+			+	+	+	+	+		+	2-60%
Verbasci flos	+			+	+	+	+	+	+			+	+		3.75-8%

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
	Comminuted herbal substances as herbal tea for oral use.

Well-established use	Traditional use
	The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used to relieve cough and symptoms associated with common cold.</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<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p>Herbal tea</p> <p>Single dose: 1.5–2 g of the herbal tea combination in 150 ml of boiling water as an herbal infusion 3 times daily.</p> <p>Daily dose: 4.5-6 g</p> <p><i>Combinations containing Althaeae radix, Anisi fructus, Foeniculi amari fructus, Lichen islandicus, Polygoni avicularis herba, Primulae flos, Sambuci flos, Thymi herba, Tiliae flos, Verbasci flos</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><i>Combinations containing Filipendula ulmaria herba, Liquiritiae radix, Salicis cortex</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>

<sup>3</sup> 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>Children between 4 and 12 years of age</i></p> <p>Combinations containing <i>Althaeae radix</i> and <i>Foeniculi amari fructus</i>, only</p> <p>Herbal tea</p> <p>Single dose: 1 g of the herbal tea combination in 150 ml of boiling water as an herbal infusion 3 times daily.</p> <p>Daily dose: 3 g</p> <p><b>Duration of use</b></p> <p>If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p><i>All combinations:</i></p> <p>Hypersensitivity to the active substance(s)</p> <p>Combinations containing <i>Anisi fructus</i>, <i>Foeniculi amari fructus</i>, additionally: Hypersensitivity to <i>Apiaceae</i> or to anethole.</p> <p>Combinations containing <i>Foeniculi amari fructus</i>, additionally: Hypersensitivity to mugwort pollen, due to the cross reactivity with fennel.</p> <p>Combinations containing <i>Filipendula ulmaria flos</i>, additionally: Hypersensitivity to salicylates.</p> <p>Combinations containing <i>Primula flos</i>, additionally: Hypersensitivity to other <i>Primula</i> species.</p> <p>Combinations containing <i>Salicis cortex</i>, additionally: Hypersensitivity to salicylates or to other NSAIDs (e.g. history of angioedema, bronchial spasm, or chronic urticaria in response to salicylates or to other NSAIDs).</p> <p>Asthma due to sensitivity to salicylates. Active</p>

Well-established use	Traditional use
	<p>peptic ulcer disease. Third trimester of pregnancy. Glucose-6-phosphate dehydrogenase deficiency. Children and adolescents under 18 years of age because of the risk of Reye's syndrome. Severe liver or renal dysfunction. Coagulation disorders.</p> <p>Combinations containing <i>Thymi herba</i>, additionally: Hypersensitivity to other plants of the Lamiaceae (Labiatae) family.</p>

#### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p><i>Combinations containing Salicis cortex:</i></p> <p><i>Combinations containing Althaea radix, Lichen islandicus, Liquiritiae radix, Plataginis folium, Primula flos, Sanbuci flos, Thymi herba or Verbasci flos:</i></p> <p>If dyspnoea, fever or purulent sputum occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing Filipendula ulmaria flos or Salici cortex:</i></p> <p>Concomitant use with salicylates and other NSAIDs is not recommended without medical advice. If fever exceeds 39°C, persists or is associated with severe headache, or if symptoms worsen 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:</i></p> <p>The use in children between 4 and 12 years of age is not recommended if the daily intake of estragole exceeds the guidance value of 1.0 µg/kg bw, unless justified by a risk assessment based on adequate safety data.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>Patients taking liquorice medication should not take other liquorice containing products as</p>

Well-established use	Traditional use
	<p>serious adverse events may occur such as water retention, hypokalemia, hypertension, cardiac rhythm disorders. Liquorice medication is not recommended to be used in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to the adverse effects of liquorice.</p> <p><i>Combinations containing Primula flos:</i></p> <p>Caution is recommended in patients with gastritis or gastric ulcer.</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 for those containing Liquiritiae radix and/or Salicis cortex:</i></p> <p>None reported.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>Liquorice root may counteract antihypertensive action of prescribed medications. Not to be used concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance.</p> <p><i>Combinations containing Salicis cortex:</i></p> <p>Willow bark may increase the effects of anticoagulants such as coumarin derivatives.</p>

#### 4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p><i>All combinations except for those containing Foeniculi amari, Liquiritiae radix and/or Salicis cortex:</i></p> <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient</p>



Well-established use	Traditional use
	<p>data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p> <p><i>Combinations containing Foeniculi amari fructus:</i></p> <p>Safety during pregnancy and lactation has not been established (see sections 5.3 'Preclinical safety data' and 6 'Pharmaceutical particulars' regarding preclinical safety data related to the content of estragole).</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>There is evidence that trans-anethole is excreted in human breast milk.</p> <p>No fertility data available.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>Studies in animals have shown reproductive toxicity.</p> <p>Not recommended (safety during pregnancy and lactation has not been established)</p> <p>No fertility data available.</p> <p><i>Combinations containing Salicis cortex:</i></p> <p>The use during the first and second trimester of pregnancy and during lactation is not recommended. Salicylates cross the placenta and appear in breast milk.</p> <p>Contraindicated in the third trimester of pregnancy.</p> <p>No fertility data available.</p>

#### 4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	<p>No studies on the effect on the ability to drive and use machines have been performed.</p>

#### 4.8. Undesirable effects

Well-established use	Traditional use
	<p><i>Combinations containing Althaea radix, Filipendula ulmaria flos, Lichen islandicus, Liquiritiae radix, Plantaginis folium, Polygoni avicularis herba, Sambuci flos, Tiliae flos, Verbasci flos:</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 Anisi fructus:</i></p> <p>Allergic reactions to aniseed affecting the skin or the respiratory system have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing Foeniculi amari fructus:</i></p> <p>Allergic reactions to fennel, affecting the skin or the respiratory system may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing Primula flos:</i></p> <p>Allergic reactions may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing Salicis cortex:</i></p> <p>Allergic reactions such as rash, pruritis, urticaria, asthma, exanthema and gastrointestinal symptoms such as, nausea, vomiting, abdominal pain, diarrhea, dyspepsia, heartburn, may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p> <p><i>Combinations containing Thymi herba:</i></p>

Well-established use	Traditional use
	Gastric disorders may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

#### 4.9. Overdose

Well-established use	Traditional use
	<p><i>All combinations except for those containing Liquiritiae radix and/or Primula flos:</i></p> <p>No case of overdose has been reported.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>Cases of overdose have been reported with prolonged use (more than 4 weeks) and/or intake of high amount of liquorice, with symptoms such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy.</p> <p><i>Combinations containing Primula flos:</i></p> <p>Overdose may lead to stomach upset, vomiting or diarrhoea.</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 data

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 Filipendula flos, Lichen islandicus, Polygoni avicularis herba, Primula flos, Salici cortex, Sambuci flos:</i></p> <p>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p><i>Combinations containing Althaea radix, Plantaginis folium, Tilia flos:</i></p> <p>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p> <p><i>Combinations containing Thymi herba, Verbasci flos:</i></p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p><i>Combinations containing Anisii fructus:</i></p> <p>An aniseed extract prepared with water was tested in an Ames test on Salmonella typhimurium strains TA98, TA100, TA102 and turned out as negative.</p> <p>Results from non-clinical studies showed a weak mutagenic potential of anethole. Anethole and its metabolites are unlikely to be genotoxic in vivo.</p> <p>The genotoxic risk related to estragole is not considered to be relevant in the specified conditions of use (short term use in adolescents, adults and elderly) due to the small amount present in herbal infusions prepared from aniseed.</p> <p><i>Combinations containing Foeniculi fructus:</i></p> <p>A fennel aqueous extract was tested in an Ames test on Salmonella typhimurium strains TA98, TA100 and turned out as negative. Results from studies carried out in laboratory animals showed a weak mutagenic activity of anethole.</p>

Well-established use	Traditional use
	<p>Several studies have shown the carcinogenic effects of estragole and some of its metabolites in mice (liver tumours) and displayed suggestive but indirect evidence of carcinogenicity in rats. Estragole is considered a genotoxic carcinogen in rodents (see section 6 'Pharmaceutical particulars' for further details).</p> <p>An aqueous extract of fennel seeds given daily to 24 female BALB/c mice from day 6 to day 15 of pregnancy showed a dose-dependent teratogenic effect. The embryotoxic effect resulted in morphological changes, skeletal disorders, and cellular alterations.</p> <p>Adequate tests on reproductive toxicity have not been performed.</p> <p><i>Combinations containing Liquiritiae radix:</i></p> <p>The risks related to Liquiritiae radix as described in the single monograph are not considered in the present monograph because they are not considered to be relevant in the specified conditions of use due to the small amount present in herbal infusions prepared with such herbal substance.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	<p><i>Combinations containing Foeniculi amari fructus:</i></p> <p>In the general population, exposure to estragole should be kept as low as practically achievable. In pregnant and breast-feeding women, the daily intake of estragole has to be below 0.05 mg/person per day. In children below 12 years of age, the daily intake of estragole has to be below 1.0 µg/kg bw.</p>

## 7. Date of compilation/last revision

20 November 2024