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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Malva sylvestris* L., flos

Draft

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BG (bulgarski): Горски слез, цвят CS (čeština): slézový květ DA (dansk): KATOSTBLOMST DE (Deutsch): Malvenblüten EL (elliniká): EN (English): mallow flower ES (español): Malva, flor de ET (eesti keel): FI (suomi): kiiltomalva, kukka FR (français): mauve HR (hrvatski): cvijet crnog sljeza HU (magyar): erdei mályva virág IT (italiano):	LV (latviešu valoda): malvas ziedi LT (lietuvių kalba): Malvas ziedi MT (Malti): Fjuri tal-Ħobbejża NL (Nederlands): Groot kaasjeskruid, bloem PL (polski): Kwiat ślazu dziki PT (português): RO (română): floare de nalbă de pădure SK (slovenčina): kvet slezu lesného SL (slovenščina): kvet slezu lesného SV (svenska): rödmalva, blomma IS (íslenska): NO (norsk):



## 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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC. <i>Malva sylvestris</i> L., flos (mallow flower) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance

## 3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for infusion or decoction preparation for oromucosal 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
	<b>Indication 1)</b> Traditional herbal medicinal product used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. <b>Indication 2)</b> Traditional herbal medicinal product used as a demulcent preparation for the symptomatic relief

<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 9<sup>th</sup>. monograph (ref.: 1541)

Well-established use	Traditional use
	<p>of mild gastrointestinal discomfort.</p> <p>The product is a traditional herbal medicinal product for use in specified indications 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><b>Indication 1)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>1 – 2 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion or in 250 ml of water as a decoction 3 times daily.</p> <p>Average daily dose: 5 g</p> <p><b>Indication 2)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Herbal tea: 1 – 2 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion or in 250 ml of water as a decoction 3 times daily.</p> <p>Average daily dose: 5 g.</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><b>Duration of use</b></p> <p><b>Indication 1)</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>Indication 2)</b></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</p>

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

Well-established use	Traditional use
	<p>consulted.</p> <p><b>Method of administration</b></p> <p>Indication 1)</p> <p>Oral and oromucosal use.</p> <p>Indication 2)</p> <p>Oral use</p>

#### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

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

Well-established use	Traditional use
	<p>Indication 1)</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>Indications 1) and 2)</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</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
	None reported.

#### 4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient

Well-established use	Traditional use
	data, the use during pregnancy and lactation is not recommended.  No fertility data available.

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

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

#### 4.8. Undesirable effects

Well-established use	Traditional use
	None known.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

#### 4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

## 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
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the

Well-established use	Traditional use
	<p>safe use of the product.</p> <p>Tests on genotoxicity, reproductive toxicity and carcinogenicity has not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

5 June 2018