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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Malva sylvestris* L. and/or *Malva neglecta* Wallr., folium

Draft

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BG (bulgarski): Слез, лист CS (čeština): DA (dansk): KATOSTBLAD DE (Deutsch): Malvenblätter EL (elliniká): EN (English): mallow leaf ES (español): ET (eesti keel): FI (suomi): kiiltomalva, lehti FR (français): mauve HR (hrvatski): list crnog sljeza HU (magyar): erdei mályva levél IT (italiano):	LV (latviešu valoda): malvas lapas LT (lietuvių kalba): Malvas lapas MT (Malti): Weraq tal-Ħobbejża NL (Nederlands): Groot kaasjeskruid, blad PL (polski): Liść ślazu PT (português): RO (română): frunză de nalbă de pădure SK (slovenčina): list slezu lesného SL (slovenščina): list slezu lesného SV (svenska): malva, blad IS (íslenska): NO (norsk):
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## 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><i>Malva sylvestris</i> L. and/or <i>Malva neglecta</i> Wallr., folium (mallow leaf)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Comminuted herbal substance for infusion or decoction preparation for oromucosal 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><b>Indication 1)</b></p> <p>Traditional herbal medicinal product used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough.</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product used as a</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 9<sup>th</sup>. monograph (ref.: 2391)

Well-established use	Traditional use
	<p>demulcent preparation for the symptomatic relief 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>5</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>1.8 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion or in 150 ml of water as a decoction 3 times daily. Daily dose: 5.4 g</p> <p><b>Indication 2)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>Herbal tea: 1.8 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion or in 150 ml of water as a decoction 3 times daily. Daily dose: 5.4 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>5</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

Well-established use	Traditional use
	<p>been established. In the absence of sufficient data, the use during 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
	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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### 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

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>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