



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2018
EMA/HMPC/749511/2016
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on European Union monographs and list (MLWP)	Nov 2016 Mar 2017 May 2017 Sep 2017 Nov 2017 Jan 2018 Mar 2018
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	5 June 2018
Start of public consultation	30 June 2018
End of consultation (deadline for comments)	28 September 2018
Adoption by HMPC Monograph (EMA/HMPC/749511/2016) AR (EMA/HMPC/749518/2016) List of references (EMA/HMPC/749540/2016) HMPC Opinion (EMA/HMPC/28616/2019)	20 November 2018
Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Malva sylvestris</i> L., flos; mallow flower



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

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
	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
	Indication 1) Traditional herbal medicinal product used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. Indication 2)

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 Ph. Eur 9th. monograph (ref.: 1541)

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used as a 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 administration³

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1)</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 2-3 times daily.</p> <p>Average daily dose: 5 g</p> <p>Indication 2)</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 2-3 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>Duration of use</p> <p>Indication 1)</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>Indication 2)</p> <p>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor</p>

³ 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>or a qualified health care practitioner should be consulted.</p> <p>Method of administration</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
	safe use of the product. Tests on genotoxicity, reproductive toxicity and carcinogenicity has not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

20 November 2018