



1 July 2014
EMA/HMPC/137299/2013
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Rosa gallica* L., *Rosa centifolia* L., *Rosa damascena* Mill., flos

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2013 July 2013
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Rosa gallica</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., flos; Rosae flos; Rose flower
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BG (bulgarski): Маслодайна роза, цвят CS (čeština): růžový květ DA (dansk): Rosenblomst DE (Deutsch): Rosenblütenblätter EL (elliniká): Ρόδου άνθος EN (English): Rose flower ES (español): Rosa, flor de ET (eesti keel): kibuvitsaõis FI (suomi): ruusu, kukka FR (français): Rose pâle, rose de Provins, rose de Damas HR (hrvatski): ružin cvijet HU (magyar): Rózsavirág IT (italiano): Rosa fiore	LT (lietuvių kalba): Rožių žiedai LV (latviešu valoda): Rožu ziedi MT (Malti): Fjura tal-Ward NL (Nederlands): Roos, bloem PL (polski): Kwiat róży PT (português): Rosa, flor RO (română): SK (slovenčina): Kvet ruže SL (slovenščina): cvet vrtnice SV (svenska): Rosenblad <i>IS (íslenska):</i> <i>NO (norsk):</i> Roseblomst
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Community herbal monograph on *Rosa gallica* L., *Rosa centifolia* L., *Rosa damascena* Mill., flos

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 as amended</p> <p><i>Rosa gallica</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., flos (Rose flower)</p> <p>i) Herbal substance</p> <p>Dried petals</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or comminuted herbal substance for infusion preparation for oromucosal or cutaneous use.</p> <p>The pharmaceutical form should be described by full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for mild inflammations of the oral and pharyngeal mucosa.</p>

¹ The material complies with the monograph in the Ph. Fr. XI edition (Rose pâle 1989; Rose rouge 1989).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	<p data-bbox="810 253 970 286">Indication 2)</p> <p data-bbox="810 309 1433 376">Traditional herbal medicinal product used for relief of minor skin inflammation.</p> <p data-bbox="810 405 1425 510">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 data-bbox="810 696 938 730">Posology</p> <p data-bbox="810 748 970 781">Indication 1)</p> <p data-bbox="810 804 1193 837"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 860 954 893"><u>Single dose</u></p> <p data-bbox="810 916 1433 1061">Herbal substance or comminuted herbal substance for infusion preparation for oromucosal use: 1 – 2 g of the herbal substance or comminuted herbal substance in 200 ml of boiling water</p> <p data-bbox="810 1084 1273 1117">As a mouth rinse, up to 3 times daily.</p> <p data-bbox="810 1140 1409 1245">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1323 970 1357">Indication 2)</p> <p data-bbox="810 1379 1193 1413"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 1435 954 1469"><u>Single dose</u></p> <p data-bbox="810 1491 1433 1637">Herbal substance or comminuted herbal substance for infusion preparation for cutaneous use: 1 – 2 g of the herbal substance or comminuted herbal substance in 200 ml of boiling water</p> <p data-bbox="810 1659 1425 1727">Apply on the affected area, up to 3 times daily, in the form of a wet, impregnated dressing.</p> <p data-bbox="810 1749 1409 1854">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</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>Duration of use</p> <p>Indications 1) and 2)</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>Method of administration</p> <p>Cutaneous use. Oromucosal 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>Indications 1) and 2)</p> <p>The use in children under 12 years of age has not been established due to lack of adequate.</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
	<p>No fertility data available.</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>

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 as amended.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on genotoxicity, reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

1 July 2014