



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 April 2014
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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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<p>BG (bulgarski): Маслодайна роза, цвят  CS (čeština): růžový květ  DA (dansk): Rosenblomst  DE (Deutsch): Rosenblütenblätter  EL (elliniká): Ρόδιου 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</p>	<p>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 (islenska):</i>  <i>NO (norsk):</i> Roseblomst</p>
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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<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 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>

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

<sup>2</sup> 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="810 280 967 313"><b>Indication 2)</b></p> <p data-bbox="810 338 1430 405">Traditional herbal medicinal product used for relief of minor skin inflammation.</p> <p data-bbox="810 432 1422 535">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 data-bbox="810 723 935 757"><b>Posology</b></p> <p data-bbox="810 835 967 869"><b>Indication 1)</b></p> <p data-bbox="810 893 1362 960"><i>Adolescents over 12 years of age, adults and elderly</i></p> <p data-bbox="810 987 954 1021"><u>Single dose</u></p> <p data-bbox="810 1046 1430 1184">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 1211 1270 1245">As a mouth rinse, up to 3 times daily.</p> <p data-bbox="810 1272 1406 1375">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 1453 967 1487"><b>Indication 2)</b></p> <p data-bbox="810 1512 1362 1579"><i>Adolescents over 12 years of age, adults and elderly</i></p> <p data-bbox="810 1606 954 1639"><u>Single dose</u></p> <p data-bbox="810 1664 1430 1803">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 1830 1422 1897">Apply on the affected area, up to 3 times daily, in the form of a wet, impregnated dressing.</p> <p data-bbox="810 1924 1398 1957">The use in children under 12 years of age is not</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>recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></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><b>Method of administration</b></p> <p>Oromucosal use. Cutaneous 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**

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

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

#### **4.9. Overdose**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose has been reported.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

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

#### **5.2. Pharmacokinetic properties**

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

#### **5.3. Preclinical safety data**

<b>Well-established use</b>	<b>Traditional use</b>
	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

15 December 2013