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SCIENCE MEDICINES HEALTH

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## Community herbal monograph on *Chamaemelum nobile* (L.) All., flos

Draft

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BG (bългарски): Италианска лайка, цвят CS (čeština): květ heřmánku římského DA (dansk): DE (Deutsch): Römische Kamille EL (elliniká): EN (English): roman chamomile flower ES (español): ET (eesti keel): vääris-vaipkakra õis FI (suomi): FR (français): camomille romaine (fleur de) HU (magyar): rómaikamilla virág IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): Romiešu kumelītes ziedi MT (malti): NL (nederlands): Roomse kamille PL (polski): Kwiat rumianu rzymskiego PT (português): RO (română): floare de mușețel roman SK (slovenčina): Kvet parumana spanilého SL (slovenščina): SV (svenska): Kamomillblomma, romersk IS (islenska): NO (norsk): kamilleblomst, romersk
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# Community herbal monograph on *Chamaemelum nobile* (L.) All., 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>Chamaemelum nobile</i> (L.) All., flos (roman chamomile flower)</p> <p>i) Herbal substance</p> <p>As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations</p> <p>Liquid extract (DER 1:1), extraction solvent ethanol 70% v/v</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance as herbal tea for oral use and for infusion preparation for oromucosal use.</p> <p>Herbal preparations in liquid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008:0380 corrected 6.0).

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

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p><b>Indication 1)</b></p> <p>Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat.</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

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>i) Herbal substance</p> <p>Oral use: 1-4 g herbal substance as infusion 3 times daily between meals.</p> <p>Oromucosal use: 2-3 g herbal substance for infusion preparation 3–4 times daily as a mouth and throat wash.</p> <p>ii) Herbal preparations</p> <p>Oral use: 1-4 ml liquid extract 3 times daily.</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 more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

Well-established use	Traditional use
	<p data-bbox="810 255 970 286">Indication 2)</p> <p data-bbox="810 315 1422 454">If the symptoms persist more than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 483 1145 515"><b>Method of administration</b></p> <p data-bbox="810 539 970 571">Indication 1)</p> <p data-bbox="810 595 927 627">Oral use.</p> <p data-bbox="810 651 970 683">Indication 2)</p> <p data-bbox="810 707 1018 739">Oromucosal use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 925 1382 1025">Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p data-bbox="810 1220 1422 1283">The use in children under 12 years of age has not been established, due to lack of adequate data.</p> <p data-bbox="810 1312 1401 1413">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1442 1422 1615">For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.</p>

### 4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	<p data-bbox="810 1845 995 1877">None reported.</p>

#### 4.6. Pregnancy and lactation

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

#### 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
	Hypersensitivity reactions of the skin have been reported. The frequency is not known.  If other adverse reactions not mentioned above 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 reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

27 January 2011