



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2010 January 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 January 2011
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Chamaemelum nobile</i> (L.) All., flos; Chamomillae romanae flos; Roman chamomile flower
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BG (bългарски): Италианска лайка, цвят CS (čeština): Květ heřmánku římského DA (dansk): Romersk kamilleblomst DE (Deutsch): Römische Kamille EL (elliniká): Αρθός χαμαιμήλου ρωμαϊκού EN (English): Roman chamomile flower ES (español): Manzanilla romana, flor de ET (eesti keel): Vääris-vaipkakra õis FI (suomi): FR (français): Camomille romaine (fleur de) HU (magyar): Rómaikamilla virág IT (italiano): Camomilla romana fiore	LT (lietuvių kalba): LV (latviešu valoda): Romiešu kumelītes ziedi MT (malti): NL (nederlands): Roomse kamille PL (polski): Kwiat rumianu rzymskiego PT (português): Macela, flor RO (română): Floare de mușețel roman SK (slovenčina): Kvet parumana spanilého SL (slovenščina): Cvet rimske kamilice SV (svenska): Kamomillblomma, romersk <i>IS (islenska):</i> <i>NO (norsk):</i> Romersk kamilleblomst
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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^{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>Chamaemelum nobile</i> (L.) All., flos (Roman chamomile flower)</p> <p>i) Herbal substance As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 70% v/v</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance and comminuted herbal substance as herbal tea for oral 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>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastro-

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

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>intestinal complaints including bloating and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Herbal tea: 1-4 g of the herbal substance or comminuted herbal substance in 100-150 ml of boiling water as a herbal infusion 3 times daily between the meals.</p> <p>Liquid extract: 1-4 ml 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>Duration of use</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 consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>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>The use in children under 12 years of age has not</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>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> <p>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
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<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> <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 reported.</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 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

22 November 2011