



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Matricaria recutita* L., flos

Final

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BG (bulgarski): Лайка, цвят CS (čeština): heřmánkový květ DA (dansk): Kamilleblomst DE (Deutsch): Kamillenblüten EL (elliniká): άνθος χαμαιμήλου EN (English): matricaria flower ES (español): Manzanilla común, flor de ET (eesti keel): kummeliõis FI (suomi): kamomilla, kukka FR (français): Matricaire (fleur de) HR (hrvatski): kamiličin cvijet HU (magyar): kamillavirágzat IT (italiano): Camomilla comune fiore	LT (lietuvių kalba): Ramunėlių žiedai LV (latviešu valoda): Kumelītes ziedi MT (Malti): Fjura tal-Kamumella NL (Nederlands): Kamille PL (polski): Kwiat rumianku PT (português): Camomila, flor RO (română): floare de mușețel SK (slovenčina): Kvet rumančeka SL (slovenščina): cvet prave kamilice SV (svenska): Kamomill, blomma <i>IS (islenska):</i> <i>NO (norsk):</i> Kamilleblomst
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European Union herbal monograph on *Matricaria recutita* L., 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>Matricaria recutita</i> L., flos (matricaria flower)</p> <p>i) Herbal substance</p> <p>As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Liquid extract (DER 1:1), extraction solvent: ethanol 96% V/V:water:ammonia solution 10% m/m (50:47.5:2.5)³</p> <p>c) Liquid extract (DER 1:4.3-5.7), extraction solvent: ethanol 96% V/V:water:ammonia solution 10% m/m (50:47.5:2.5)³</p> <p>d) Liquid extract (DER 1:1), extraction solvent: ethanol 48% V/V:ammonia solution 10% m/m (39:1)³</p> <p>e) Liquid extract (DER 1:1), extraction solvent: ethanol 45% V/V:ammonia solution 10% m/m (14.7:1)</p> <p>f) Dry extract (DER 4-7:1), extraction solvent: ethanol 50% m/m</p> <p>g) Liquid extract (DER 1:1.7-2.6), extraction solvent: ethanol 48% V/V</p> <p>h) Liquid extract (DER 1:1), extraction solvent: ethanol 55% V/V</p> <p>i) Liquid extract (DER 1:2), extraction solvent: ethanol 70% V/V</p> <p>j) Liquid extract (DER 1:4.1-4.6), extraction solvent: ethanol 55% V/V:Poloxamer 188 (993:3)</p> <p>k) Liquid extract (DER 1:1.8-2.1), extraction solvent: ethanol 52% V/V:macrogol hydroxystearate (99.5:0.5)</p>

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. monograph (ref.: 0404).

³ The material complies with the Ph. Eur. monograph (ref.: 1544).

Well-established use	Traditional use
	l) Liquid extract (DER 1:4-4.5) extraction solvent: ethanol 38.5% m/m (containing 1.36% sodium acetate trihydrate, 0.45% sodium ascorbate and 0.41% sodium hydroxide) m) Liquid extract (DER 2.7-5.5:1), extraction solvent: ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) n) Dry extract (DER 11-16:1), extraction solvent: ethanol 95.4% V/V (containing 0.22% sodium acetate, 0.12% sodium hydroxide) o) Liquid extract (DER 1:2-2.8), extraction solvent: propan-2-ol 48% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or comminuted herbal substance as herbal tea for oral use and inhalation.</p> <p>Herbal preparations in liquid dosage forms for oral use.</p> <p>Herbal substance or comminuted herbal substance for infusion preparation for oromucosal or cutaneous use.</p> <p>Herbal preparations in liquid dosage forms for preparation of dilutions for oromucosal or cutaneous use.</p> <p>Herbal preparations in liquid dosage forms for preparation of dilutions for steam inhalation.</p> <p>Herbal preparations in semi-solid dosage forms for cutaneous use.</p> <p>Herbal preparations in liquid dosage forms for use as bath additives.</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
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for the symptomatic treatment of minor gastro-intestinal complaints such as bloating and minor spasms.</p>

Well-established use	Traditional use
	<p>Indication 2) Traditional herbal medicinal product used for the relief of symptoms of common cold.</p> <p>Indication 3) Traditional herbal medicinal product for the treatment of minor ulcers and inflammations of the mouth and throat.</p> <p>Indication 4) Traditional herbal medicinal product used for adjuvant therapy of irritations of skin and mucosae in the anal and genital region, after serious conditions have been excluded by a medical doctor.</p> <p>Indication 5) Traditional herbal medicinal product used for the treatment of minor inflammation of the skin (sunburn), superficial wounds and small boils (furuncles).</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 administration⁴

Well-established use	Traditional use
	<p>Posology</p> <p>Preparation a)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 1.5-4 g of the herbal substance or comminuted herbal substance in 150 ml of boiling water as a herbal infusion Daily dose: 3-4 times</p> <p><i>Children (6 months - 2 years)</i> Single dose: 0.5-1.0 g Daily dose: 2-4 times</p> <p><i>Children (2-6 years)</i> Single dose: 1.0-1.5 g Daily dose: 2-4 times</p> <p><i>Children (6-12 years)</i> Single dose: 1.5-3.0 g Daily dose: 2-4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 3-10 g of herbal substance or comminuted herbal substance in 100 ml hot water for inhalation</p>

⁴ 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>Daily dose: several times</p> <p><i>Children (6-12 years)</i> Single dose: 2-5 g of herbal substance or comminuted herbal substance in 100 ml hot water for inhalation Daily dose: 1-2 times</p> <p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: Herbal substance or comminuted herbal substance for infusion preparation for oromucosal use: 1-5 g in 100 ml water, for rinsing and gargling Daily dose: several times</p> <p>Indication 4) <i>Adolescents, adults and elderly</i> Single dose: 4.5-5 g herbal substance or comminuted herbal substance per 1 l water for infusion preparation for irrigation Daily dose: several times</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 3-10 g herbal substance or comminuted herbal substance in 100 ml water for infusion preparation for washings and impregnated dressings Daily dose: several times</p> <p>Preparation b)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 2 g in 150 ml warm water Daily dose: 3-4 times</p> <p>Preparation c)</p> <p>Indication 3) (for gargling or rinsing)</p> <p>Indication 5) (for washing or impregnated dressings)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 10 ml in 150 ml warm water Daily dose: 3-4 times</p> <p>Preparation d)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 3 ml in 150 ml water Daily dose: 3-4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 1 ml in 100 ml hot water for inhalation Daily dose: 1-2 times</p>

Well-established use	Traditional use
	<p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: 1 ml in 100 ml water for gargling or rinsing Daily dose: several times</p> <p>Indication 4) <i>Adolescents, adults and elderly</i> Single dose: 1 ml in 100 ml water for irrigations Single dose: 5 ml per 1 l water for partial baths Daily dose: several times</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 1.5 ml in 150 ml water for compresses and irrigation Daily dose: several times</p> <p>Preparation e)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 150 ml water Daily dose: up to 4 times</p> <p><i>Children (6-12 years)</i> Single dose: 2.5 ml in 150 ml water Daily dose: up to 4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 150 ml hot water for inhalation Daily dose: several times</p> <p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: 2.5 ml in 125 ml water for gargling or rinsing Daily dose: 3-4 times</p> <p>Indication 4) <i>Adolescents, adults and elderly</i> Single dose: 20 ml per 1 l water for compresses and irrigation Single dose: 10 ml per 1 l water for partial baths Daily dose: several times</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 20 ml per 1 l water for compresses and irrigation Single dose: 10 ml per 1 l water for partial baths Daily dose: several times</p> <p>Preparation f) (in diluted liquid dosage forms containing approximately 0.47% dry extract)</p> <p>Indication 5) (sun burn) <i>Adolescents, adults and elderly</i> Single dose: apply few drops in a thin layer on the</p>

Well-established use	Traditional use
	<p>affected area Daily dose: several times</p> <p>Preparation g)</p> <p>Indication 1) and 3) <i>Adolescents, adults and elderly</i> Single dose 1.5 ml in 150 ml water for oral use and mouth rinsing or gargling Daily dose: 3-4 times</p> <p><i>Children (6-12 years)</i> Single dose: 0.7–1 ml in 150 ml water for oral use and mouth rinsing or gargling Daily dose: 3-4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 15 ml per 1 l hot water for inhalation Daily dose: 1-2 times</p> <p>Indication 4) and 5) <i>Adolescents, adults and elderly</i> Single dose: 15 ml per 1 l hot water for compresses and irrigation or partial baths Daily dose: several times</p> <p>Preparation h)</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 15 ml per 1 l hot water for inhalation Daily dose: 1-3 times</p> <p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: 1-2 ml in 150 ml warm water for mouth rinsing or gargling Daily dose: up to 4 times</p> <p><i>Children (6-12 years)</i> Single dose: 0.5-1 ml in 150 ml warm water mouth rinsing or gargling Daily dose: up to 4 times</p> <p>Indication 4) and 5) <i>Adolescents, adults and elderly</i> Single dose: 15 ml per 1 l warm water for compresses and irrigation Single dose: 15-30 ml per 5 l warm water for partial baths Daily dose: one to several times</p> <p>Preparation i)</p> <p>Indication 1) and 3) <i>Adolescents, adults and elderly</i> Single dose: 2.5-5 ml in 50-100 ml water Daily dose: 3-4 times</p>

Well-established use	Traditional use
	<p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 5-10 ml in 100 ml water for washings and compresses Daily dose: several times</p> <p>Preparation j)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 150 ml warm water Daily dose: 3-4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 40 ml per 1 l hot water for inhalation Daily dose: 1-2 times</p> <p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 100 ml water for rinsing or gargling Daily dose: 3 times</p> <p>Indication 4) <i>Adolescents, adults and elderly</i> Single dose: 20 ml per 1 l water for hip baths Single dose: 40 ml per 1 l water for washings and impregnated dressings Daily dose: one to several times</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 40 ml per 1 l water for irrigations and impregnated dressings Daily dose: one to several times</p> <p>Preparation k)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 1 g in 150 ml water Daily dose: up to 4 times</p> <p><i>Children (6-12 years)</i> Single dose: 0.7 g in 150 ml water Daily dose: up to 4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 10-20 ml per 1 l hot water for inhalation Daily dose: one to several times</p> <p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: 0.7-1.0 ml in 75 ml water for rinsing or gargling Daily dose: one to several times</p>

Well-established use	Traditional use
	<p>Indication 4) <i>Adolescents, adults and elderly</i> Single dose: 7.5-15 ml per 1 l water for partial baths and irrigations Daily dose: one to several times daily</p> <p>Indication 5) <i>Adolescents, adults and elderly</i> Single dose: 10-20 ml per 1 l water for washing, impregnated dressings and partial baths Daily dose: one to several times daily</p> <p>Preparation l)</p> <p>Indication 1) <i>Adolescents, adults and elderly</i> Single dose: 5 ml in 100 ml water Daily dose: up to 4 times</p> <p><i>Children from (6-12 years)</i> Single dose: 2-3 ml in 100 ml water Daily dose: up to 4 times</p> <p>Indication 2) <i>Adolescents, adults and elderly</i> Single dose: 20 ml per 1 l hot water for inhalation Daily dose: 1-2 times</p> <p>Indication 3) <i>Adolescents, adults and elderly</i> Single dose: 5 ml per 100 ml warm water for rinsing or gargling Daily dose: 3 to several times</p> <p>Indication 4) and 5) <i>Adolescents, adults and elderly</i> Single dose: 45 ml per 1 l water for washings, impregnated dressings and irrigations Daily dose: 1-2 times</p> <p>Single dose: 30 ml per 1 l water for partial bath or hip bath Daily dose: 1-2 times</p> <p>Preparation m) in semi-solid dosage forms (corresponding to app. 8% herbal substance)</p> <p>Indication 4) and 5) <i>Children (4 weeks - 12 years), adolescents, adults and elderly</i> Single dose: apply a thin layer on the affected area. Daily dose: 2-3 times</p> <p>Preparation n) in semi-solid dosage forms (corresponding to app. 5.5% herbal substance).</p> <p>Indication 4) and 5) <i>Adolescents, adults and elderly</i> Single dose: apply a thin layer on the affected area.</p>

Well-established use	Traditional use
	<p>Daily dose: several times</p> <p>Preparation o)</p> <p>Indication 4) and 5)</p> <p><i>Adolescents, adults and elderly</i> Single dose: 20 ml per 1 l for compresses and irrigation Daily dose: one to several times</p> <p>Single dose: 20-40 ml in 20-40 l water for partial baths Daily dose: one time</p> <p>Single dose: 30 ml in 150 l water for full baths Daily dose: one time</p> <p><i>Children (4 weeks - 12 years)</i> Single dose: 10-20 ml in 10-20 l water for baths Daily dose: one time</p> <p>For all herbal preparations</p> <p>The use is not recommended in specific age groups as specified in 4.4 'special warnings and precautions for use'.</p> <p>Duration of use</p> <p>If the symptoms persist more than one 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>Indication 1) Oral use.</p> <p>Indication 2) Inhalation.</p> <p>Indication 3) Oromucosal use.</p> <p>Indication 4) and 5) Cutaneous use, Use as bath additive</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> <p>Use as bath additive:</p> <p>Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.</p> <p>Partial baths or hip baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever and severe infections.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>All methods of administration</p> <p>The use of the herbal preparations b, c, d, f, i, j, and n in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 1)</p> <p>The oral use of the herbal tea for children below 6 months of age has not been established due to general considerations of nutrition and fluid intake.</p> <p>The oral use of herbal preparations e, g, k, l in children under 6 years of age has not been established due to lack of adequate data.</p> <p>The oral use of herbal preparations b, d, i, j in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 2)</p> <p>The use of herbal preparations d, e, g, h, j, k, l as steam inhalation in children under 12 years of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparation a as steam inhalation in children under 6 years of age has not been established due to lack of adequate data.</p> <p>Indication 3)</p> <p>The use of herbal preparation h, for mouth washes or gargling in children under 6 years of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations a, c, d, e, i, j, k, l, for mouth washes or gargling in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 4)</p> <p>The use of herbal preparation o, m for partial baths or local cutaneous use in children under 4 weeks of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations a, d, e, g, h, j, k, l, n for partial baths or local cutaneous use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 5)</p> <p>The use of herbal preparation m, o, for partial baths or local cutaneous use in children under 4 weeks of age has not been established due to lack of adequate data.</p> <p>The use of herbal preparations a, c, d, e, f, g, i, j, k, l, n (partially) for partial baths or local cutaneous 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</p>

Well-established use	Traditional use
	<p>medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>For tinctures and preparations 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>Oral use: For patients after renal transplantation taking high dosages for longer periods (about two months) interactions based on effects on CYP450 have been reported.</p> <p>Cutaneous, oromucosal use, inhalation, or as bath additive: None reported.</p>

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Preparation a) Safety during pregnancy and lactation has been established.</p> <p>If applicable before nursing the baby the nipples should be cleaned of matricaria containing products for cutaneous use to prevent a sensitization of the baby.</p> <p>Preparation b) to o) 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
	Hypersensitivity reactions including severe allergic reaction (dyspnoea, Quincke's disease, vascular

Well-established use	Traditional use
	collapse, anaphylactic shock) following mucosal contact with liquid chamomile preparations 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. Adequate 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

7 July 2015