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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Matricaria recutita* L., aetheroleum

Draft

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Community herbal monograph on *Matricaria recutita* L., aetheroleum

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., aetheroleum (matricaria oil)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparation a) Essential oil</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in liquid dosage forms for use as a bath additive.</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>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>

¹The 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. 01/2008: 1836).

Well-established use	Traditional use
	The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>Use as bath additive: 0.5 – 1 mg per litre Full bath: approximately 100 litre Partial bath or hip bath: 20 – 50 litre</p> <p>Average daily dose</p> <p>Full bath: one bath per day or every other day Partial bath or hip bath: one or two times per day</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>Duration of bath: 10 – 20 minutes</p> <p>If the symptoms persist longer 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>Cutaneous use as bath additive: Recommended temperature of bath: 35 – 38 °C</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.

Well-established use	Traditional use
	<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
	The use in children under 12 years of age has not been established due to lack of adequate data.

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
	Hypersensitivity reactions including severe allergic reaction (dyspnoea, Quincke's disease, vascular collapse, anaphylactic shock) following mucosal

Well-established use	Traditional use
	<p>contact with liquid chamomile preparations have been reported. The frequency is not known.</p> <p>If other adverse reactions not mentioned above 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
	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

1 July 2014