



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Viola tricolor* L. and/or subspecies *Viola arvensis* Murray (Gaud) and *Viola vulgaris* Koch (Oborny), herba cum flore

Draft

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Rediscussion in Working Party on Community monographs and Community list (MLWP)	
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Community herbal monograph on *Viola tricolor* L. and/or subspecies *Viola arvensis* Murray (Gaud) and *Viola vulgaris* Koch (Oborny), herba cum flore

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>Viola tricolor</i> L. and/or species <i>Viola arvensis</i> Murray (Gaud.) and <i>Viola vulgaris</i> Koch (Oborny), herba cum flore (wild pansy, heartsease)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use or for infusion preparation for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The material complies with the Ph. Eur. monograph (ref.: 01/2008: 1855).

² 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>Traditional herbal medicinal product for symptomatic treatment of mild seborrhoeic skin condition.</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>Posology</p> <p><i>Adolescents and adults</i></p> <p>a) Oral use</p> <p>Herbal tea: 3 g of comminuted herbal substance in 250 ml of boiling water as an infusion 1-3 times daily.</p> <p>b) Cutaneous use</p> <ul style="list-style-type: none">- 5-20 g/L of comminuted herbal substance as an infusion. Apply as a wet dressing to the affected areas of the skin 2-3 times daily.- Bath additive: 5-10 g/L of comminuted herbal substance as an infusion. 1 litre of infusion to be added to the bath. <p>The use in children under 12 years of the age is not recommended (see section 4.4. 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Oral use</p> <p>Not be used for more than 2 weeks.</p> <p>Cutaneous use</p> <p>Cutaneous dressings 2-3 times daily for 1 week.</p> <p>Full baths should only be taken after a doctor or a qualified health care practitioner has been consulted.</p> <p>Method of administration</p>

Well-established use	Traditional use
	Oral use. Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance, or to salicylates. Cutaneous use Open wounds, large areas of damaged skin.

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. Hot baths should not be used in case of febrile or infectious illnesses, in heart insufficiency and hypertension.

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

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	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
	<p>One case of haemolysis in a child with G6PD deficiency has 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
	<p>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.</p> <p>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

6 May 2010