EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2010
EMA/HMPC/131734/2009
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

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2009 September 2009 November 2009 January 2010
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BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch):	NL (nederlands):
EL (elliniká):	PL (polski): fiołek trójbarwny
EN (English): wild pansy, heartsease	PT (português):
ES (espanol):	RO (română):
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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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended V*iola tricolor* L. and/or species *Viola arvensis* Murray (Gaud.) and *Viola vulgaris* Koch (Oborny), herba cum flore (wild pansy, heartsease) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

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

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**
	Traditional herbal medicinal product for symptomatic treatment of mild seborrhoeic skin conditions. 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**
	Posology *Adults and elderly* Oral use Herbal tea: 3 g of comminuted herbal substance as an infusion 1-3 times daily. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). *Adolescents, adults and elderly* Cutaneous use 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. The use in children under 12 years of the age is not recommended (see section 4.4. 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration**

	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**
	Oral use The use in children and adolescent under 18 years of age has not been established due to lack of adequate data. Cutaneous 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**
	Safety during pregnancy nad 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**
	One case of haemolysis in a child with G6PD deficiency has been reported after oral administration. 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

25 November 2010