European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

COMMUNITY HERBAL MONOGRAPH ON *CALENDULA OFFICINALIS* L., FLOS

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2007 July 2007
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KEYWORDS Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Calendula officinalis* L.; Calendulae flos; calendula flowers

[1] Changes introduced in sections 4.2 and 4.3

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *CALENDULA OFFICINALIS* L., FLOS

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Calendula officinalis* L., flos (calendula flower) i) Herbal substance Whole or cut, dried, fully opened flowers, which have been detached from the receptacle, of the cultivated, double-flowered varieties. ii) Herbal preparations A) Liquid extract (1:1), extraction solvent ethanol 40-50% (v/v) B) Liquid extract (1:1.8-2.2), extraction solvent ethanol 40-50% (v/v) C) Tincture (1:5), extraction solvent ethanol 70-90% (v/v) D) Liquid extract (1:10), extraction solvent fatty vegetable oil e.g. olive oil E) Ointment (1:5 – 1:25), extraction solvent hardened vegetable fat, petroleum jelly[4] F) Comminuted herbal substance

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance or comminuted herbal substance for infusion or other herbal preparations in liquid or semi solid dosage forms for cutaneous and oromucosal use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[2] The material complies with the Ph. Eur. monograph (ref. 01/2005:1297).

[3] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[4] Calendula ointment is prepared by gentle digestion of the herbal substance in the melted ointment base for up to 16 hours and subsequent filtration and congealment during fall in temperature.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	a) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds. b) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology i) Herbal substance Infusion for cutaneous and oromucosal application: 1-2 g / 150 ml of water. The still warm infusion is used as such to rinse or gargle for the treatment of inflammations in the mouth or the throat or to prepare impregnated dressings. ii) Herbal preparations A) Liquid extract (DER 1:1) In semi-solid dosage forms: amount equivalent to 2-10% herbal substance B) Liquid extract (DER 1:1.8-2.2) In semi-solid dosage forms: amount equivalent to 2-5% herbal substance C) Tincture (DER 1:5) In impregnated dressings diluted at least 1:3 with freshly boiled water; in semi-solid dosage forms: amount equivalent to 2-10% herbal substance As a gargle or mouth wash in a 2% solution D) Liquid extract (DER 1:10) In semi-solid dosage forms: amount equivalent to 2-8% herbal substance E) Ointment Equivalent to 4-20% herbal substance Indication a) The use is not recommended in children under 6 years of age (see section 4.4 Special warnings and precautions for use).

	Indication b) The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). 2 to 4 times daily **Duration of use** Impregnated dressings: remove after 30-60 minutes All herbal preparations: If the symptoms persist after 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Cutaneous and oromucosal use.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication a) The use in children under 6 years of age is not recommended because there is no experience available. Indication b) The use in children under 12 years of age is not recommended because there is no experience available. If signs of skin infection are observed, a doctor or a qualified health care practitioner should be consulted.

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 and 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
	Not relevant.

4.8. Undesirable effects

Well-established use	Traditional use
	Skin sensitization. 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. Available tests on genotoxicity (liquid extract with 60% ethanol) and on carcinogenicity (undefined extract) did not give any reason for concern. Tests on reproductive toxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

8 May 2008