EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Calendula officinalis* L., flos

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	May 2007 July 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	5 July 2007
End of consultation (deadline for comments).	15 October 2007
Re-discussion in MLWP	January 2008 March 2008
Adoption by HMPC Monograph (EMEA/HMPC/179281/2007) AR (EMEA/HMPC/179282/2007) List of references (EMEA/HMPC/ 261882/2007) Overview of comments received during the public consultation (EMEA/HMPC/590044/2007) HMPC Opinion (EMEA/HMPC/590995/2007)	6 March 2008
First systematic review	
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BG (bulgarski): Невен, цвят CS (čeština): měsíčkový květ DA (dansk): Morgenfrueblomst DE (Deutsch): Ringelblumenblüten EL (elliniká): ἀνθος καλέντουλας- ανθός καλενδούλης EN (English): calendula flower ES (español): caléndula, flor de ET (eesti keel): saialilleõisik FI (suomi): tarhakehäkukka, kukka FR (français): souci HR (hrvatski): nevenov cvijet HU (magyar): körömvirág IT (italiano): calendula fiore	LT (lietuvių kalba): Medetkų žiedai LV (latviešu valoda): Kliņģerītes ziedi MT (Malti): fjura tas-Suffejra NL (Nederlands): Goudsbloem, bloem PL (polski): kwiat nagietka PT (português): maravilhas, flor RO (română): floare de gălbenele SK (slovenčina): kvet nechtíka SL (slovenščina): cvet vrtnega ognjiča SV (svenska): ringblomma, blomma IS (íslenska): morgunfrú,blóm NO (norsk): ringblomst

European Union 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[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Calendula officinalis* L., flos (calendula flower) i) Herbal substance As defined in the Ph. Eur. monograph ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (1:1), extraction solvent ethanol 40-50% (V/V) c) Liquid extract (1:1.8-2.2), extraction solvent ethanol 40-50% (V/V) d) Tincture (1:5), extraction solvent ethanol 70-90% (V/V) e) Liquid extract (1:10), extraction solvent fatty vegetable oil e.g. olive oil f) Extract (1:5 – 1:25), extraction solvent hardened vegetable fat, petroleum jelly

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance or comminuted herbal substance for infusion for oromucosal or cutaneous use. Herbal preparations in liquid or semi solid dosage forms 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.01/2011: 1297) declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[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
	Indication 1) 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. Indication 2) 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 the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology Indication 1) *Children, adolescents, adults and elderly* a) Single dose: 1-2 g herbal substance or comminuted herbal substance in 150 ml water. The still warm infusion is used to prepare impregnated dressings Daily dose: 2 to 4 times b) In semi-solid dosage forms: amount equivalent to 2-10% herbal substance c) In semi-solid dosage forms: amount equivalent to 2-5% herbal substance d) Diluted at least 1:3 with freshly boiled water; used to prepare impregnated dressings; in semi-solid dosage forms: amount equivalent to 2-10% herbal substance e) In semi-solid dosage forms: amount equivalent to 2-8% herbal substance f) In semi-solid dosage forms: amount equivalent to 4-20% herbal substance

[3] 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
	For all preparations b) to f) Single dose: apply a thin layer of semi-solid preparation to the affected area Daily dose: 2 to 4 times The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) *Adolescents, adults and elderly* a) Single dose: Herbal substance or comminuted herbal substance for infusion preparation for oromucosal use: 1-2 g in 150 ml water; the still warm infusion is used for rinsing and gargling Daily dose: 2 to 4 times Preparation d) As a gargle or mouth wash in a 2% solution Daily dose: 2 to 4 times The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) Impregnated dressings: remove after 30-60 minutes If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Indication 1) Cutaneous use Indication 2) Oromucosal use

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1) The use in children under 6 years of age has not been established due to lack of adequate data. If signs of skin infection are observed or the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) 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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

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

Well-established use	Traditional use
	Skin sensitization has 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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. Available tests on genotoxicity (liquid extract with 60% ethanol) did not give any reason for concern. Adequate tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation / last revision

27 March 2018