



London, 5 July 2007  
Doc. Ref. EMEA/HMPC/179283/2007

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**COMMUNITY LIST ENTRY ON *CALENDULA OFFICINALIS* L., FLOS**

<b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	July 2007
<b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>	5 July 2007
<b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>	15 October 2007
<b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>	
<b>ADOPTION BY HMPC</b>	

Comments should be provided using this [template](#) to [hmpc.secretariat@emea.europa.eu](mailto:hmpc.secretariat@emea.europa.eu)  
Fax: +44 20 75 23 70 51

<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Calendula officinalis</i> L.; Calendulae flos; calendula flower
-----------------	---

**ENTRY TO LIST OF HERBAL SUBSTANCES, PREPARATIONS AND  
COMBINATIONS THEREOF FOR USE IN  
TRADITIONAL HERBAL MEDICINAL PRODUCTS:**

***CALENDULA OFFICINALIS* L., FLOS**

<b>Scientific name of the plant</b>	
<i>Calendula officinalis</i> L., flos	
<b>Botanical family</b>	
Asteraceae	
<b>Herbal substance</b>	
Calendula flower	
<b>Common name in all EU official languages of herbal substance</b>	
<div> <div> BG (bългарски):  CS (čeština): měsíčkový květ  DA (dansk):  DE (Deutsch): Ringelblumenblüten  EL (elliniká):  EN (English): calendula flower  ES (español): Caléndula, flor de  ET (eesti keel): saialilleõisik  FI (suomi): kehäkukka  FR (français): Souci  HU (magyar): </div> <div> IT (italiano):  LT (lietuvių kalba):  LV (latviešu valoda):  MT (malti):  NL (nederlands): Goudsbloem  PL (polski): kwiat nagietka  PT (português):  RO (română):  SK (slovenčina): Nechtíkový kvet  SL (slovenščina): cvet vrtnega ognjiča  SV (svenska):   IS (íslenska): morgunfrú,blóm  NO (norsk): </div> </div>	
<b>Herbal preparation(s)</b>	
A) Liquid extract (DER 1:1, ethanol 40-50% v/v) B) Tincture (DER 1:5, ethanol 70-90% v/v) C) Liquid extract (DER 1:10, fatty vegetable oil, e.g. olive oil) D) Ointment (DER 1:5 – 1:25, hardened vegetable fat, petroleum jelly <sup>1</sup> ) E) Comminuted herbal substance for infusion	
<b>European Pharmacopoeia monograph reference</b>	
Calendula flower - Calendulae flos 01/2005:1297	

<sup>1</sup> 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

Indication(s)
<p>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.</p> <p>b) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>
Type of tradition
European
Specified strength
<p>Herbal substance:  Infusion for topical 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 compresses.</p> <p>Herbal preparations:  A) Liquid extract (DER 1:1, ethanol 40-50% v/v)  In semi-solid dosage forms: amount equivalent to 2-10% herbal substance  B) Tincture  In compresses diluted at least 1:3 with freshly boiled water; in semi-solid dosage forms: amount equivalent to 2-10% herbal substance  C) Liquid extract (DER 1:10, fatty vegetable oil e.g. olive oil)  In semi-solid dosage forms: amount equivalent to 2-8% herbal substance  D) Ointment  Equivalent to 4-20% herbal substance</p>
Specified posology
<p>Please see 'Specified strength'</p> <p><b>Indication a)</b>  The use is not recommended in children under 6 years of age (see below Special warnings and precautions for use).</p> <p><b>Indication b)</b>  The use is not recommended in children under 12 years of age (see below Special warnings and precautions for use).</p>
Route of administration
Topical application, 2 to 4 times daily.
Duration of use or any restrictions on the duration of use
<p>Compresses: remove after 30-60 minutes</p> <p>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.</p>

## **Any other information necessary for the safe use**

### **Contraindications**

Hypersensitivity to members of the Asteraceae family (Compositae family).

### **Special warnings and precautions for 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, medical advice should be sought.

### **Interactions with other medicinal products and other forms of interaction**

None reported.

### **Pregnancy and lactation**

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

### **Effects on ability to drive and use machines**

Not relevant.

### **Undesirable effects**

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.

### **Overdose**

None reported.

### **Pharmaceutical particulars [If necessary]**

Not applicable.

### **Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]**

Not applicable.