

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Weleda Calendula Cuts and Grazes Skin Salve Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of ointment contains:

0.20 ml of tincture from *Calendula officinalis* L., herba (Calendula herb) (equivalent to 100 mg of Calendula herb).

Extraction solvent: Ethanol 86 % w/w.

Excipients with known effect:

1g of ointment contains 324 mg of Wool Fat (Lanolin)

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Ointment.

A smooth, soft, cream to pale yellow ointment.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

A traditional herbal medicinal product used for minor wounds, cuts and grazes. Exclusively based on long standing use.

### 4.2 Posology and method of administration

For cutaneous use only

Adults, the elderly and children over 6 years:

Wash hands before and after use.

Clean the affected area and apply to the affected area directly or on a dry dressing two to three times daily.

Duration of use

Do not use for more than one week.

If symptoms worsen, persist or do not improve after one week of use of Weleda Cuts & Grazes Skin Salve Ointment a qualified healthcare practitioner or health care professional eg a doctor or pharmacist should be consulted.

The use is not recommended in children under 6 years of age (See section 4.4 Special Warnings and Precautions for Use)

### 4.3 Contraindications

Hypersensitivity to *Calendula officinalis*, other species of the Asteraceae (Compositae) family or any of the other ingredients of the product listed in section 6.1.

### 4.4 Special warnings and precautions for use

Do not exceed the stated dose.

Since no data on the safe use in children are available, the use in children under 6 years of age is not recommended.

If symptoms worsen, persist or do not improve after one week, a qualified healthcare practitioner or health care professional eg a doctor or pharmacist should be consulted.

If signs of skin infection are observed, a qualified healthcare practitioner or health care professional eg a doctor or pharmacist should be consulted.

Discontinue use if redness, irritation or dry skin occurs.  
Avoid contact with the eyes or mucous membranes.

Contains Wool Fat (Lanolin). May cause local skin reactions (e.g. contact dermatitis).

## **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed

## **4.6 Fertility, pregnancy and lactation**

The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

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

Not relevant.

## **4.8 Undesirable effects**

Skin sensitisation has been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a qualified healthcare practitioner or health care professional eg a doctor or pharmacist should be consulted.

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## **4.9 Overdose**

No case of overdose has been reported.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Not required as per Article 16c (1)(a)(iii) of Directive 2001/83/EC as amended.

## **5.2 Pharmacokinetic properties**

Not required as per Article 16c (1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Tests on reproductive toxicity, genotoxicity or carcinogenicity have not been performed.

Available tests on genotoxicity (liquid extract with 60% ethanol) and on carcinogenicity (undefined extract) did not give any reason for concern.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

*Herbal Preparation:*

Ethanol  
Purified Water

*Ointment:*

Wool Fat (anhydrous lanolin)  
Refined Sunflower Oil  
Virgin Olive Oil  
Yellow Beeswax  
Wool Alcohols

6.2 Incompatibilities

Not applicable

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

25 g internally lacquered, collapsible aluminium tubes with a membrane nozzle and latex seal with white HDPE pierce screw cap.

6.6 Special precautions for disposal

No special requirements

7 REGISTRATION HOLDER

Weleda (UK) Limited  
Heanor Road  
Ilkeston  
Derbyshire DE7 8DR  
United Kingdom

8 REGISTRATION NUMBER(S)

TR0407/003/001

**9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION**

Date of first registration: 28th July 2017

**10 DATE OF REVISION OF THE TEXT**