Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Weleda HyperCal Wound Salve Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of ointment contains:
0.10 ml of tincture from *Calendula officinalis* L., herba (Calendula herb) (equivalent to 50 mg of Calendula herb) Extraction solvent Ethanol 86% w/w and
0.15 ml of tincture from *Hypericum perforatum* L., herba (St John's Wort herb) (equivalent to 50mg of St John's Wort herb) Extraction solvent Ethanol 86% w/w.

Excipients with known effect:
1 g 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, buff to pale yellow ointment with a faint characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used for the relief of painful cuts and minor wounds. Exclusively based on longsanding use.

4.2 Posology and method of administration

For cutaneous use only.

Adults, the elderly and children over 12 years:

Wash hands before and after use.

Clean the affected area and apply directly or on a dry dressing two or 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 HyperCal Wound 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 12 years of age (See Section 4.4 Special warnings and precautions for use).

4.3 Contraindications

Hypersensitivity to the active ingredients, 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 12 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.

During the treatment intense UV-exposure of the respective skin areas should be avoided.

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.

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; E-mail: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.

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

For *Hypericum perforatum* – Studies on acute toxicity and repeated dose toxicity did not show signs of toxic effects.

The weak positive results of an ethanolic extract in the Ames-test (Salmonella typhimurium TA 98 and TA 100, with and without metabolic activation) could be assigned to quercetin and are irrelevant to human safety. No signs of mutagenicity could be detected in further in-vitro and in-vivo test systems.

Tests on reproductive toxicity revealed equivocal results.

Tests on the carcinogenic potential have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparations:
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)

TR0407/002/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 28th July 2017

10 DATE OF REVISION OF THE TEXT