Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hypericum/Calendula Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of ointment contains 0.068ml of tincture from *Calendula officinalis* L., herb (Calendula) (1:19.6) and 0.102ml of tincture from *Hypericum perforatum* L., herv (St. John's Wort) (1:19.8)

Extraction solvent for *Calendula officinalis* L., herb: Ethanol 43%w/w
Extraction solvent for *Hypericum perforatum* L., herb: Ethanol 62%w/w

Contains wool fat.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous Ointment

A smooth buff to pale yellow cutaneous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal remedy used for the relief of painful cuts and minor wounds.

4.2 Posology and method of administration

For cutaneous use only.
Adults, the elderly and children:
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 or persist after one week, a doctor or qualified healthcare professional 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 or to plants of the Asteraceae family or to any of the excipients.

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 or persist after one week, a doctor or qualified healthcare professional should be consulted.

If signs of skin infection are observed, a doctor or qualified healthcare professional should be consulted.
Discontinue if redness, irritation or dry skin occurs.
Avoid contact with the eyes and 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 (eg. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

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 sensitization has been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare professional 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

Whilst pharmacological particulars are not normally applicable to a product of this nature where the active ingredients are the whole herbal extracts, research supports the traditionally recognised herbal activities.

According to the literature, the pharmacological actions of the ingredients are predominantly anti-microbial, vulnerary and anti-inflammatory.

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

Purified Water
Wool Alcohols
Yellow Beeswax
Wool Fat
Olive Oil, Virgin
Sunflower Seed Oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Internally lacquered collapsible aluminium tube with nozzle and latex seal containing 25 g ointment.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0407/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th October 1993

Date of last renewal: 29th October 2008

10 DATE OF REVISION OF THE TEXT

November 2015