Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Weleda Arnica Bumps and Bruises Skin Salve Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of ointment contains:
0.10 ml of tincture (DER 1:2) from fresh Arnica montana L., planta tota (Arnica whole plant) (equivalent to 48 mg of fresh Arnica whole plant);

Extraction solvent: Ethanol 53% 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, soft, cream to pale yellow ointment with a faint odour characteristic of Arnica.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used for the relief of muscular aches, pain, stiffness, sprains, bruises, swelling after contusions and minor sports injuries. Exclusively based on long-standing use.

4.2 Posology and method of administration

For cutaneous use only.
Adults, the elderly and children:
Wash hands before and after use.
Muscular pain, stiffness, sprains, bruises and minor sports injuries: apply sparingly to the affected area with gentle massage three to four times daily.
Contusions: Apply a small amount immediately at the site of the injury
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 Bumps & Bruises Skin Salve Ointment a qualified healthcare practitioner or health professional eg a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to *Arnica montana*, 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.
If symptoms worsen, persist or do not improve after one week, a doctor or qualified healthcare practitioner or health professional eg a doctor or pharmacist should be consulted.
If articular pain accompanied by swelling of joint, redness or fever are present a doctor should be consulted.
Do not use on broken or irritated skin.
Avoid contact with eyes or mucous membranes.
Discontinue use if redness, irritation or dry skin occurs.
Contains Wool fat (Lanolin). May cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interactions

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

Hypersensitivity (contact dermatitis, itching skin rash) has been reported. The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner or health 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.
In the unlikely event of internal ingestion, due to the irritant effect of the product, symptoms of intoxication may include gastro-intestinal and nervous system disturbances; dizziness, diarrhoea, shivering and palpitations. Respiratory difficulties may occur at very high doses. Treatment of overdose: the stomach should be emptied by aspiration or lavage if the patient has not already vomited. Demulcent drinks such as milk should be given.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparation:
Ethanol
Purified Water

Ointment:
Wool Fat
Refined Sunflower Oil
Virgin Olive Oil

Yellow Beeswax
Wool Alcohols
Ethanol
Purified Water

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 container.

6.5 Nature and contents of container

25g 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) Ltd
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Derbyshire DE7 8DR,
United Kingdom

8 REGISTRATION NUMBER(S)

TR0407/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 14th December 2018

10 DATE OF REVISION OF THE TEXT

11 DOSIMETRY

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS