Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Massage Balm with Arnica

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of cutaneous liquid contains 480 mg of extract from *Arnica montana* L., flos, (equivalent to 22 mg of Arnica flower) and *Betula pendula* Roth and/or *Betula pubescens* Ehrh., folium, as well as hybrids of both species (equivalent to 22 mg of Birch leaf).
Extraction solvents: ethanol 96 % v/v and refined sunflower oil

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Oil.
A clear yellow-green oil with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal remedy for the symptomatic relief of rheumatic pain, muscular pain and stiffness, backache, fibrositis, bruising, cramp and sprains.

Traditionally used topically as an anti-inflammatory agent.

4.2 Posology and method of administration

Adults: Apply sparingly to the affected area with gentle massage three to four times daily.

Elderly Patients: The normal adult application is appropriate.

Children: The normal adult application is appropriate.

Special Groups: None Known.

4.3 Contraindications

Hypersensitivity to any ingredient, particularly known sensitivity to *Arnica montana L.*
Hypersensitivity to members of the Compositae family of plants.

4.4 Special warnings and precautions for use

Contact sensitisation is a rare occurrence.

Do not apply where the skin is broken.

Cutaneous oil. For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

None known. No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy: There is no evidence as to the safety of the product in human pregnancy, nor is there any evidence from animal studies. Although no adverse reactions have been observed, the use of the product in pregnancy is best avoided unless under the guidance of a medical practitioner.

Lactation: There is no evidence to suggest that this product should not be used during lactation.

4.7 Effects on ability to drive and use machines

None known. No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Contact sensitization has been reported very rarely.

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. There are no grounds for supposing that any adverse effects would result from single or repeated excessive topical application of this product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmcotherapeutic group M02AX10 (WHO)

Whilst pharmacological particulars are not normally applicable to a product of this nature where the active ingredients are prepared from the whole herbs, in the form of oil extract or essential oil, research supports the traditionally recognised herbal activities.

All the ingredients of the product have been traditionally used in the treatment of rheumatic and muscular pain, bruising and sprains. According to the literature, the pharmacological actions of the ingredients predominantly include anti-inflammatory, rubefacient, and counter-irritant effects.

5.2 Pharmacokinetic properties

No information in this area currently available.

5.3 Preclinical safety data

This product has been on the market in the UK for over 25 years. This section is not therefore applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparation
Refined Sunflower Oil
Ethanol 96 %

Cutaneous liquid
Refined Sunflower Oil
Rosemary Oil
Lavender/Lavandin oil blend

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years
The product should not be used later than three months after opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Green glass bottle, white screw cap and red spout ring.
Pack size 50ml

Green glass bottle, white screw cap and red spout ring.
Pack size 100ml

Green glass bottle, white screw cap and red spout ring.
Pack size 200ml

Not all pack sizes may be marketed

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0407/021/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th October 1992

Date of last renewal: 12th October 2007

10 DATE OF REVISION OF THE TEXT

April 2017