IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0407/001/001
Case No: 2038411

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Weleda (UK) Limited

Heanor Road, **Ilkeston**, **Derbyshire DE7 8DR**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Arnica Ointment.

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **04/11/2007**.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arnica Ointment.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100g of ointment contains 10mL of tincture from *Arnica montana* L., planta tota (Arnica, whole plant) (1:2)

Extraction solvent: Ethanol 30% w/w

Contains Wool Fat.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

Pale yellow cutaneous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of muscular pain, stiffness, sprains, bruises and swelling after contusions. Immediate application at the site of a contusion helps to prevent the development of bruising.

4.2 Posology and method of administration

Adults: Muscular pain, stiffness, sprains and bruises: 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.
Children: The adult dose is appropriate.
Elderly: The adult dose is appropriate.
Pregnancy and lactation: The adult dose is appropriate.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

If redness or itching occur, discontinue use.

For external use only.
Do not apply where the skin is broken.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 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.

4.8 Undesirable effects

Contact sensitization has been reported very rarely.

4.9 Overdose

There are no known data on overdose. 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

Whilst pharmacological particulars are not normally applicable to a product of this nature where the active ingredient is the whole herbal extract, research has shown that certain constituents of *Arnica montana* possess anti-inflammatory properties.

5.2 Pharmacokinetic properties

No information in this area is currently available.

5.3 Preclinical safety data

This product has been marketed for over 35 years. This section is not therefore applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool alcohols
Yellow beeswax
Wool fat
Olive oil
Refined Sunflower oil
Ethanol

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

25 g and 6 g internally lacquered collapsible aluminium tubes with a membrane nozzle and latex seal.

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

No special requirement.

7 MARKETING AUTHORISATION HOLDER

Weleda (UK) Ltd
Heanor Road
Iikeston
Derbyshire
DE7 8DR
United Kingdom
info@weleda.co.uk

8 MARKETING AUTHORISATION NUMBER

PA 407/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th November 1992
Date of last renewal: 4th November 2007

10 DATE OF REVISION OF THE TEXT

September 2009