

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0407/005/001

Case No: 2021991

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

Calendolon Ointment 20%v/v Calendula officinalis 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 **11/10/2006**.

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

Calendolon Ointment 20% v/w Calendula Officinalis Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

20 ml tincture of *Calendula officinalis* L fresh plant (1=2) in 43% w/w ethanol per 100g ointment.

Excipient: Contains 32% w/w wool fat

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

A smooth, homogeneous, pale yellow cutaneous ointment, with a faint odour characteristic of wool fat.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of cuts, minor wounds and abrasions.

For topical application only.

4.2 Posology and method of administration

Cleanse the affected area and apply to the affected part direct or on a dry dressing two or three times daily until the condition clears.

Children and the elderly: For the above conditions where applicable to these groups, there is no difference in the dosage between children, adults and the elderly.

4.3 Contraindications

Hypersensitivity to the active substance *Calendula officinalis tincture*, or to the excipients lanolin or beeswax.

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Pregnancy: For Calendula officinalis tincture no clinical data on exposed pregnancies is available. Animal studies donot indicate direct or indirect harmful effects with respect to pregnancy, embryonal/ foetal development, postuntion or postnatal development (see 5.3.) Caution should be used when prescribing to pregnant wemen.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Contact sensitisation has been reported.
MeDRA class 021: Frequency 005.

4.9 Overdose

There is 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

Phamacotheapeutic group: Preparations fo rthe treatment of wounds and ulcers.
ATC code: D03
No information in this area is presently available.

5.2 Pharmacokinetic properties

No information in this area is presently available.

5.3 Preclinical safety data

This product has been marketed for over 30 years. This section is therefore not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ointment base contains:
Wool alcohols
Yellow Beeswax
Wool Fat (Anhydrous lanolin)
Olive oil, virgin
Sunflower oil, refined

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Four years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

25g and 6g collapsible aluminium tubes internally lacquered, with plastic screw cap closure.

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 requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 407/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th October 1991

Date of last renewal: 11th October 2006

10 DATE OF REVISION OF THE TEXT

October 2006