

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0407/025/001

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

Calendula Lotion, 40% v/v Concentrate for Cutaneous Solution

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

Calendula Lotion 40% v/v Concentrate for Cutaneous Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients per 100 ml:

40 ml of an ethanolic tincture of *Calendula officinalis L Herba* (1=2 in 43% w/w alcohol).

Excipients: Ethanol content of the lotion 46% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for cutaneous solution or mouthwash.

Calendula Lotion is a clear, pale yellow to yellow-green, mobile liquid with a faint characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- (1) As a traditional herbal antiseptic and promoter of healing of minor cuts, wounds and abrasions of the skin.
- (2) As a mouthwash, (currently not marketed).

4.2 Posology and method of administration

- (1) Dilute 1 teaspoonful (5 ml) in a glassful (200ml) of cooled boiled water.
Apply to the affected area after cleansing.
- (2) Dilute 1 teaspoonful (5 ml) in ½ glassful (100ml) of cooled boiled water.

4.3 Contraindications

Use in patients known to be sensitive to *Calendula officinalis L*.

4.4 Special warnings and precautions for use

In the case of sensitivity to *Calendula officinalis L*.

If there is no improvement or aggravation of the condition consult the doctor.

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 do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/ foetal development, postnatal or postnatal development (see 5.3.) Caution should be used when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Local irritation and redness may occur.
MeDRA class 021: Frequency 005.

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

Pharmacotherapeutic group: Preparations for the treatment of wounds and ulcers.
ATC code: D03
No information in this area 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 35 years. This section is therefore not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 90%
Purified Water Ph.Eur.

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

50 and 100 ml amber glass bottles fitted with a dropper insert and a tamper evident 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
Derbs DE7 8DR
England

8 MARKETING AUTHORISATION NUMBER

PA 407/25/1

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