

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1175/012/001

Case No: 2062971

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

Medlock Medical Ltd

Tubiton House, Medlock Street, Oldham, OL1 3HS, United Kingdom

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

Steripaste 15%w/w Medicated Paste Bandage

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 **26/07/2009**.

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

Steripaste 15% w/w Medicated Paste Bandage

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide 15% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Impregnated dressing

Bandage with serrated edges evenly impregnated with white opaque, homogeneous paste, packed in heat-sealed sachets of laminated foil in cartons.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of venous ulcers where sensitisation has been a problem.

4.2 Posology and method of administration

Adults, Children and the Elderly

Frequency of dressing changes is at the discretion of the responsible physician.

(Differentiation between patients of differing age groups is less important when considering the dosage regime than the apparent healing rate of the wound/condition).

4.3 Contraindications

Hypersensitivity to an ingredient of the paste and acute eczematous lesions.

Use in large surface wounds or burns.

4.4 Special warnings and precautions for use

Avoid use on grossly macerated skin. One of the functions of occlusive bandages is to increase absorption. Care should be taken, therefore, if it is decided to apply topical steroid preparations under these bandages as their absorption may be significantly increased.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No special precautions required.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D09AB01 - Zinc bandage without supplements.

The product is a paste bandage with the active constituent presented in an aqueous/oil based emulsion paste, spread onto a cotton bandage.

Zinc Oxide as a Zinc salt has astringent properties and has been shown to play a role in wound healing.

Much of the therapeutic action of paste bandages is attributable to the bandaging technique, the physical support and protection provided, and to the maintenance of moist wound healing conditions.

5.2 Pharmacokinetic properties

The pharmacokinetics of the active ingredient are those relevant to topical application of the substances through whole or broken skin.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E422)
Fractionated Coconut Oil
Aluminium Magnesium Silicate
Xanthan Gum (E415)
Polysorbate 80 (E433)
Sorbitan Oleate (E494)
Synthetic Spermacti
Purified Water
Open-wove cotton bandage

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Store at or below 25° C in a dry place.

6.5 Nature and contents of container

Individually wrapped in waxed paper within a sealed aluminium foil/polythene bag and cardboard carton. Each carton contains one bandage (7.5. cm x 6 cm).

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

Medlock Medical Ltd
Tubiton House
Medlock Street
Oldham
OL1 3HS
UK

8 MARKETING AUTHORISATION NUMBER

PA 1175/12/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 July 1999

Date of last renewal: 26 July 2009

10 DATE OF REVISION OF THE TEXT

September 2009