IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1410/046/001
Case No: 2043649

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

Transferred from PA0021/049/001.

Bayer Limited

The Atrium, **Blackthorn Road**, **Dublin 18**, **Ireland**

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

Germolene 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 **14/05/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Germolene Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The ointment contains the following active substances:

Zinc Oxide 6.55% w/w, Methyl Salicylate 3% w/w, Phenol 1.19% w/w and Octafonium Chloride 0.3% w/w.

Excipients: Also contains wool fat (lanolin), 35.0% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment
A pink smooth ointment with characteristic medicated odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic and analgesic for the topical treatment of superficial skin trauma, nappy rash, sunburn and painful muscles.

4.2 Posology and method of administration

Minor cuts and grazes etc.:
Clean the wound and apply directly or on a dressing.

Minor burns, scalds and blisters:
Apply liberally and cover with a light bandage.

Sore, rough skin, wash-day hands, sunburn etc.:
Apply directly and rub in gently.

Stiff, aching muscles:
Apply liberally and massage in thoroughly.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

For external use only.
If symptoms persist, consult your doctor.
Keep out of the reach of children.

Prolonged used without medical supervision could be harmful.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Use in pregnancy and lactation is not contraindicated. However, as with all medicines during pregnancy, caution should be exercised.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Tartrazine (E102) and Ponceau 4R (E124) may cause allergic reactions.

Wool fat may cause local skin reactions (e.g. contact dermatitis).

4.9 Overdose

It is very unlikely that overdose would occur with this pharmaceutical form. Theoretically, frequently repeated topical applications on the same site could lead to skin irritation. However, since the product is only intended for minor skin trauma, extensive exposure is unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc oxide is a mild astringent. Methyl salicylate is a topical analgesic and anti-inflammatory. Phenol is an antiseptic and local anaesthetic. Octafonium chloride is an antiseptic. Anhydrous lanolin, yellow soft paraffin, white soft paraffin, light liquid paraffin and starch all have emollient properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no pertinent data not already described elsewhere in this SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool fat
Paraffin, Yellow soft
White Soft Paraffin
Paraffin, Light Liquid
Maize Starch
Menthol, Racemic
Colours: Ponceau 4R (E124) & Tartrazine (E102)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

This medicinal product does not require any special storage precautions. Replace closure firmly after use.

6.5 Nature and contents of container

Flexible aluminium tube, unlacquered internally, fitted with an integral nozzle and polypropylene cap, containing 27g of ointment.

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

Bayer Ltd
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1410/46/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

May 2010