IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0281/076/001
Case No: 2082845

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

Pinewood Laboratories Ltd, T/A Pinewood Healthcare

Ballymacarbry, **Clonmel**, **Co. Tipperary**, **Ireland**

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

Canazole Clotrimazole Cream 1% w/w

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 **19/05/2010**.

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

Canazole Clotrimazole Cream 1% w/w.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains 1 g clotrimazole.
Excipient: cetostearyl alcohol.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
A smooth white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is recommended for the treatment of fungal skin infections due to:

- Candida most commonly candida albicans. Mucocutaneous candidiasis (thrush) of the vulvovaginal region. Candidal infection associated with intertriginous dermatitis, vaginal discharge and nappy rash.
- Dermatophytoses such as ringworm and tinea pedis (athletes foot), tinea capitis, tinea corpis and tinea cruris.
- Commensal yeast infections eg. Pityriasis versicolor (tinea versicolor).

4.2 Posology and method of administration

Canazole Clotrimazole Cream should be thinly and evenly applied to the affected area twice daily. Treatment should be continued for at least one month for dermatophyte infections and dermal Candidal infections. For patients with tinea versicolor twice daily application for two weeks will usually be sufficient.
If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

All possibly infected areas should be treated at the same time.
Recurrence of vaginal candidiasis is common and this is frequently attributed to reinfection by the male sexual partner. In such circumstances treatment of the male partner is recommended.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Clotrimazole on pregnancy or on the health of the foetus/newborn child. To date, no other relevant epidemiological data is available.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side-effects with clotrimazole cream are very rare. If patients experience irritation, rash or itching which persists or becomes intolerable they should discontinue use immediately.

4.9 Overdose

In the unlikely event of substantial oral ingestion, routine measures such as gastric lavage should be performed as soon as possible after ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use, Imidazole derivatives
ATC Code: D01A C01
Clotrimazole has two distinct mechanisms of action. At low concentrations it exerts a fungistatic effect on susceptible fungi. This is due to inhibition of the cytochrome P450 14-α demethylase, an essential enzyme in ergosterol synthesis. As a result the de novo synthesis of sterols for cell membrane production which occurs in actively growing organisms is disrupted. In addition, consequent to the enzyme inhibition, an accumulation of lanosterol following this is thought to act as a negative feedback control of ergosterol synthesis. The resultant depletion of ergosterol from the cytoplasmic material essential for maintenance of fungal integrity. There is a concentration-dependent scale of inhibition of sterol synthesis, with reduction of fungal growth observed at low concentrations and complete inhibition at the MIC and fungicidal effects at 5-10 fold the MIC.

5.2 Pharmacokinetic properties

Clotrimazole = 1-[(2-Chlorophenyl) diphenylmethyl]-1 H-imidazole. It is an imidazole derivative and is used as an antimycotic and has wide spectrum antifungal activity. Clotrimazole shows very little absorption into the systemic circulation following dermal application. It penetrates the epidermis including the stratum corneum, the stratum spinosum and the stratum basale papillare. Less than 0.5% of applied activity is excreted in the urine. Following intravaginal administration, some studies have reported minimal absorption of clotrimazole.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan monostearate
Polysorbate
Cetostearyl alcohol
Cetyl palmitate
Octyldodecanol
Benzyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years unopened and 6 weeks once opened.

6.4 Special precautions for storage

Do not store above 25 ºC.

6.5 Nature and contents of container

Aluminium tubes containing 20 g and 50 g.

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

Pinewood Laboratories Ltd
trading as:
Pinewood Healthcare
Ballymacarbry, Clonmel
Co Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 0281/076/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 December 2000

Date of last renewal: 08 December 2005

10 DATE OF REVISION OF THE TEXT

May 2010