IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0021/004/006
Case No: 2038189

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

Bayer PLC

Bayer House, **Strawberry Hill**, **Newbury**, **Berkshire RG14 1JA**, **United Kingdom**

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

Canesten Dermatological Powder

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 **26/07/2007** until **20/09/2008**.

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

Canesten Dermatological Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clotrimazole 1% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous powder
White, fine powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Canesten Dermatological Powder should be used as an adjunct in the management of infections caused by microorganisms sensitive to clotrimazole and as a prophylactic against re-infection.

4.2 Posology and method of administration

Canesten Dermatological Powder should be sprinkled onto the infected areas two to three times daily after using Canesten Cream or Canesten Dermatological Spray. The powder may also be dusted inside articles of clothing and footwear which are in contact with the infected area.

4.3 Contraindications

Hypersensitivity to clotrimazole or the excipients rice starch.

4.4 Special warnings and precautions for use

All possibly infected areas should be treated at the same time.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Well-conducted epidemiological studies indicate no adverse effects of clotrimazole on pregnancy or on the health of the foetus/newborn child.

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

Rarely, patients may experience local mild burning or irritation immediately after applying the powder. Very rarely the patient may find this intolerable and stop treatment.

Other undesirable effects:

Body as a whole: allergic reaction, pain.

Skin and appendages: pruritis, rash.

4.9 Overdose

In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D01A C01.

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity.

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

Pharmacodynamic effects

Clotrimazole has a broad antimycotic spectrum for action *in vitro* and *in vivo*, which includes dermatophytes, yeast, moulds, etc

Under appropriate test conditions, the MIC values for these types of fungi are in the regions of less than 0.062-4(-8) micrograms/ml substrate. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In-vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on *Trichomonas vaginalis*, gram-positive microorganisms (streptococci/staphylococci) and gram-negative microorganisms (Bacteroides/*Gardnerella vaginalis*). It has no effect on lactobacilli.

In vitro, clotrimazole inhibits the multiplications of corynebacteria and gram-positive cocci- with the exception of enterococci- in concentrations of 0.5-10 micrograms/ml substrate and exerts a trichomonacidal action at 100 micrograms/ml.

Primarily resistance variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal applications have shown that clotrimazole is practically not absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 micrograms/ml, reflecting that clotrimazole applied topically does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Rice Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

Polyethylene powder canister with a perforated conical plug for dusting and a screw cap. The canister contains 30g of powder.

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 plc
Bayer House
Strawberry Hill
Newbury, Berkshire
RG14 1JA.
United Kingdom

Trading as Bayer plc, Consumer Care Division

8 MARKETING AUTHORISATION NUMBER

PA 21/4/6

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 September 1978

Date of last renewal: 21 September 2003

10 DATE OF REVISION OF THE TEXT

September 2005