IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0021/004/003
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 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 **26/07/2007**.

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 Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains clotrimazole 1.0% w/v (equivalent to 10mg/ml).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A broad spectrum antifungal for use in the topical treatment of infections due to superficial dermatophytes, Candida species and other fungi sensitive to the anti-infective: Trichomonas, Staphylococci and Bacteroides. The drug has no effect on Lactobacilli.

4.2 Posology and method of administration

Canesten solution should be thinly and evenly applied to the affected area 2 or 3 times daily. To prevent relapse, treatment should be continued for at least two weeks after the disappearance of all signs of infection.

4.3 Contraindications

Hypersensitivity to clotrimazole or Macrogol 400.

4.4 Special warnings and precautions for use

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

4.5 Interaction with other medicinal products and other forms of interaction

There have been reports of a heat reaction when Canesten Solution is used concomitantly with Sofradex drops in the ear.

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 solution. Very rarely the patient may find this irritation 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 of 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) µg/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 multiplication of Corynebacteria and gram-positive cocci- with the exception of Enterococci- in concentrations of 0.5-10 µg/ml substrate and exerts a trichomonacidal action at 100 µg/ml.

Primarily resistant 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 application 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 microg/ml, reflecting that clotrimazole applied topically does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to the information in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White opaque 20 ml HDPE bottle with PE dropper insert and PE screw-on cap.

Pack size: 20 ml.

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
England

Trading as: Bayer plc, Consumer Care Division

8 MARKETING AUTHORISATION NUMBER

PA 21/4/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2007

10 DATE OF REVISION OF THE TEXT

July 2007