IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0002/007/009
Case No: 2035298

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

Bristol-Myers Squibb Pharmaceuticals Ltd

Swords, **Co. Dublin**, **Ireland**

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

Mycostatin 100,000 Units/4g Vaginal Cream

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 **01/04/2007**.

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

Mycostatin 100,000 Units/4g Vaginal Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g application contains 100,000 units nystatin.

Excipients: each 4g application contains 0.856g propylene glycol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal cream.
Off-white to pale yellow smooth soft vanishing-type cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The treatment of vaginal infections due to *Candida albicans*.

4.2 Posology and method of administration

Adults:

Insert 1 or 2 applications (of 4g each) high into the vagina for 14 consecutive nights, or longer, regardless of any intervening menstrual period.

Children:

Vulvovaginal candidosis is rarely a problem in children. It is suggested that the vaginal cream is the most acceptable formulation for children.

Elderly:

No specific dosage recommendations or precautions.

4.3 Contraindications

There are no known contraindications to the use of nystatin.

4.4 Special warnings and precautions for use

In the therapy of Candidal infections all potential sites of infection should be treated simultaneously.

Avoid contact between the cream and contraceptive diaphragms and condoms, since the rubber may be damaged by the preparation.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There is no evidence that nystatin is absorbed systemically from the vagina. However, as with all drugs, caution should be exercised in pregnancy. Care should be taken while using the applicator to prevent the possibility of mechanical trauma.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Mycostatin Vaginal Cream is well tolerated and no substantiated sensitivity reactions have been associated with its use. Some transient local discomfort may be experienced.

4.9 Overdose

Since the absorption of nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Nystatin is an antifungal antibiotic active against a wide range of yeasts and yeast-like fungi, including *Candida albicans*.

5.2 Pharmacokinetic properties

Nystatin is formulated in oral and topical dosage forms and is not systemically absorbed from any of these preparations.

5.3 Preclinical safety data

No further relevant information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide, hydrated
Antifoam emulsion (dimeticone)
Benzyl alcohol
Macrogol ether (Promulgen Type D)
Hydrochloric acid dilute
Sodium hydroxide
Propylene glycol
Liquid sorbitol (non-crystallising)
Purified water
White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25 °C. Do not freeze.

6.5 Nature and contents of container

60 g aluminium tube with polyethylene closure, packed in a cardboard carton with a polyethylene vaginal applicator.

6.6 Special precautions for disposal and other handling

Dilution of the vaginal cream is not recommended as this may reduce therapeutic efficacy.

7 MARKETING AUTHORISATION HOLDER

Bristol-Myers Squibb Pharmaceuticals Limited
Swords
County Dublin

8 MARKETING AUTHORISATION NUMBER

PA 2/7/9

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

February 2009