

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0002/007/002

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/g 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

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/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 100,000 units of nystatin.

Excipients: each gram of cream contains - 0.266g propylene glycol, and 0.01g 1,2 benzenedicarboxylic acid, diethyl ester.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
Smooth, homogeneous, light yellow to buff coloured cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of cutaneous and mucocutaneous mycoses, particularly those caused by *Candida Albicans*.

4.2 Posology and method of administration

Adults and children:

To be applied two to four times daily.

Elderly:

No specific dosage recommendations or precautions.

4.3 Contraindications

There are no known contra-indications for topical application of nystatin.

4.4 Special warnings and precautions for use

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

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No specific precautions apply; systemic absorption is negligible.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects include allergic reactions and local irritation. Erythema multiforme has been rarely reported.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Actions:

Nystatin is a polyene, 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 gel
Antifoam emulsion (dimeticone)
Benzyl alcohol
Macrogol ether
*Perfume verley (E-91)
Propylene glycol
Liquid sorbitol (non-crystallising)
Titanium dioxide (E171)
White soft paraffin
Purified water

* (containing 1,2 benzenedicarboxylic acid, diethyl ester)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Aluminium tubes of 15 g with polyethylene closures.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bristol-Myers Squibb Pharmaceuticals Ltd
Swords
County Dublin

8 MARKETING AUTHORISATION NUMBER

PA 2/7/2

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