

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Mycostatin Ointment

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Ointment.

Smooth, homogeneous, shiny yellow-amber ointment.

#### 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 infection 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 reaction 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

Liquid paraffin  
Polyethylene resin

## 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

Aluminium tubes of 15 g with polyethylene closure.

**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**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Bristol-Myers Squibb Pharmaceuticals Ltd  
Swords  
County Dublin

**8 MARKETING AUTHORISATION NUMBER**

PA 2/7/1

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 April 1977  
Date of last renewal: 01 April 2002

**10 DATE OF REVISION OF THE TEXT**

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