Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycostatin Pastilles 100,000 Units

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oral pastille containing 100,000 units Nystatin.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Pastille
Yellow to light brown, circular pastilles, 15mm in diameter, with one face flat and the other slightly curved. The pastilles have an odour of aniseed and cinnamon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The prevention and treatment of oral candidosis.

4.2 Posology and method of administration

Adults:
No food or drink should be taken for five minutes before or one hour after consumption of the pastilles.

The usual total daily dosage is 100,000 units (1 pastille) to be sucked four times daily, for 7-14 days.

Children and the Elderly:
No specific dosage recommendations or precautions.

4.3 Contraindications

Contra-indicated in patients with a history of hypersensitivity to any of the components.

4.4 Special warnings and precautions for use

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

This medicine contains sugar. This should be kept in mind for patients with diabetes mellitus or disaccharide intolerance.

Mycostatin oral pastilles should not be used for the treatment of systemic mycoses.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Animal reproductive studies have not been conducted with nystatin.

It is not known whether nystatin can cause foetal harm when administered to pregnant women; however absorption of nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved.

Though gastro-intestinal absorption is insignificant, it is not known whether nystatin is excreted in human breast milk and caution should be exercised when nystatin is prescribed for nursing women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Nystatin is generally well tolerated by all age groups, even during prolonged use. Rarely, oral irritation or sensitisation may occur. Nausea has been reported occasionally during therapy.

Large oral doses of nystatin have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting. Rash, including urticaria, has been reported rarely. Steven-Johnson Syndrome has been reported very rarely.

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

Sucrose
Glucose Monohydrate
Liquid Glucose
Gelatin
Silicone Antifoam Emulsion
Cinnamon Bark Oil, Ceylon

Anise Oil
Potassium Hydroxide
Concentrated Hydrochloric Acid
Capol 4348 (contains: Triglycerides, Medium Chain and Beeswax, White)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Carton containing bag of paper/polythene/foil/polythene laminate, each containing 28 pastilles.

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

Bristol-Myers Squibb Pharmaceuticals Limited
Swords
County Dublin

8 MARKETING AUTHORISATION NUMBER

PA 2/7/10

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 August 1984

Date of last renewal: 14 August 2004

10 DATE OF REVISION OF THE TEXT

September 2006