Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mycostatin 100,000 units/ml Oral Suspension (Ready-Mixed)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of suspension contains 100,000 units nystatin.
Excipients: sucrose, ethanol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216)
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension

Product imported from the UK:
Light creamy, yellow suspension with a cherry mint odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The prevention and treatment of mycotic infections due to *Candida albicans*, affecting the oral cavity, oesophagus and intestinal tract

4.2 Posology and method of administration

Adults:

For the treatment of denture sores, and oral infections in adults caused by *C.albicans*, 1ml of the suspension should be dropped into the mouth four times daily; it should be kept in contact with the affected areas as long as possible.

Children:

In intestinal and oral candidosis (thrush) in infants and children, 1ml should be dropped into the mouth four times a day. The longer the suspension is kept in contact with the affected area in the mouth, before swallowing, the greater will be its effect.
For prophylaxis in the newborn the suggested dose is 1ml once daily.

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

Mycostatin Oral Suspension should not be used for treatment of systemic mycoses.
This medicine contains sugar.
In the therapy of Candidal infections, all potential sites of infections should be treated simultaneously.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, 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 a 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. Stevens-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

Cherry flavour
Cinnamic aldehyde
Ethanol
Glycerin
Methyl parahydroxybenzoate (E218)
Peppermint oil
pH adjusters (hydrochloric acid, sodium hydroxide)
Propyl parahydroxybenzoate (E216)
Sodium carboxymethylcellulose
Sodium phosphate
Sucrose
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25° C.
Do not freeze.
Store in the original container

6.5 Nature and contents of container

30ml Type III amber glass bottle with polypropylene cap, packed in a cardboard carton with a graduated, polyethylene dropper with natural rubber bulb.

6.6 Special precautions for disposal and other handling

Shake well before use.
Dilution is not recommended as this may reduce therapeutic efficacy.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/216/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2009

10 DATE OF REVISION OF THE TEXT

April 2011