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 with known effect:
Sucrose, Methyl parahydroxybenzoate (E218), Propyl parahyrdroxybenzoate (E216)

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
Product imported from Spain:
Opaque, light creamy, yellow suspension.

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*, 1 ml 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, 1 ml 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 1 ml once daily.

Elderly:
No specific dosage recommendations or precautions.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Mycostatin Oral Suspension should not be used for treatment of systemic mycoses.

This medicine contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose –galactose malabsorption or sucrose -isomaltase insufficiency should not take this medicine.

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

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose.

This medicinal product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause (possibly delayed) allergic reactions.

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. If irritation or sensitisation develops, treatment should be discontinued.

The table below lists all adverse events. The list is presented by system organ class and frequency, which is defined using the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Event (MedDRA)
Gastrointestinal Disorders	Uncommon	Diarrhoea, abdominal discomfort, nausea, vomiting
Immune System Disorders	Rare	Hypersensitivity, angioedema, including facial oedema
Skin and Subcutaneous Tissue Disorders	Rare Uncommon	Stevens-Johnson syndrome; Urticaris Rash

4.9 Overdose

Since the absorption of nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity. Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use. ATC code: D01 AA01

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 long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or its effect on male or female fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Ethanol (96%)
Carmellose Sodium
Cinnamic Aldehyde
Peppermint Essence
Imitation Cherry Flavour
Anhydrous Sodium Hydrogen Phosphate
Glycerol
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Hydrochloric Acid
Sodium Hydroxide
Purified 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.

Shelf life after first opening the bottle: 7 days

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

60ml bottle with polypropylene cap, packed in a cardboard carton with a graduated, polyethylene dropper with natural rubber bulb.

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

Shake well before use.

Dilution is not recommended as this may reduce therapeutic efficacy.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/171/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th September 2012

10 DATE OF REVISION OF THE TEXT

June 2014