

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ready mixed oral suspension containing 100,000 units nystatin per ml.

Excipient(s) with known effect:

Ethanol (8.06 mg/ml),
Sucrose (500 mg/ml),
Sodium (1 mg/ml),
Methyl parahydroxybenzoate (E218, 1.0 mg/ml),
Propyl parahydroxybenzoate (E216, 0.2 mg/ml).

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

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. Consideration should be given to official guidance on the appropriate use of antifungal agents.

4.2 Posology and method of administration

Posology

Neonates (from birth to 1 month):

Clinical studies of limited size in neonates, including preterm and babies of low weight at birth, indicate that 1 ml (100,000 U) three times daily is an effective regimen.

Infants (1 month to 2 years):

The recommended dose is one to two mL (100,000 to 200,000 units nystatin) four times daily.

Children (over 2 years) and adults:

Dosage ranges of one to six mL (100,000 to 600,000 units nystatin) four times daily have been used. It is recommended to keep the medication in contact with the affected areas as long as possible.

Older people:

No specific dosage recommendations or precautions.

In the prevention and treatment of candidiasis, the dosage regimen for Mycostatin should be continued for at least 48 hours after symptoms have disappeared. If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be reevaluated, and alternate therapy considered.

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.

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

This medicine contains 182 mg of alcohol (ethanol) in 24 ml (corresponding to 6 ml four times daily; 24 ml is the maximum dose delivered) which is equivalent to 0.76 g in 100 ml. The amount in 24 ml of this medicine is equivalent to less than 4.6 ml of beer or 1.8 ml of wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 0.5 g of sucrose per ml. This should be taken into account in patients with diabetes mellitus.

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

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

This medicine 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

Pregnancy

Animal reproductive studies have not been conducted with nystatin.

It is not known whether nystatin can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity, 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 potential risk to the foetus.

Breast-feeding

It is not known whether nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when nystatin is prescribed for a nursing woman.

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 ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ 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)
<i>Immune System Disorders</i>	Rare	Hypersensitivity, angioedema, including facial oedema
<i>Gastrointestinal Disorders</i>	Uncommon	Diarrhoea, abdominal discomfort, nausea, vomiting
<i>Skin and Subcutaneous Tissue Disorders</i>	Rare	Stevens-Johnson syndrome; Urticaris
	Uncommon	Rash

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

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: Intestinal Antiinfectives. ATC code: A07AA02.

Nystatin is an antifungal antibiotic active against a wide range of yeasts and yeast-like fungi, including *Candida albicans*.

5.2 Pharmacokinetic properties

Absorption

Nystatin is formulated in oral and topical dosage forms and is not systemically absorbed from any of these preparations.

Gastrointestinal absorption of nystatin is insignificant.

Elimination

Most orally administered nystatin is passed unchanged in the stool.

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

Cherry flavour

Cinnamic aldehyde

Ethanol

Glycerol

Methyl parahydroxybenzoate (E218),

Peppermint oil

pH adjusters (hydrochloric acid, sodium hydroxide)

Propyl parahydroxybenzoate (E216)

Sodium carboxymethylcellulose (E466)

Anhydrous disodium phosphate

Sucrose

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

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

30 ml in a bottle, packed in a cardboard carton with a graduated (in 0,5 ml steps) syringe and an adapter.

6.6 Special precautions for disposal and other handling

Shake well before use.

Dilution is not recommended as this may reduce therapeutic efficacy.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Substipharm
24 Rue Erlanger
75016 Paris
France

8. MARKETING AUTHORISATION NUMBER

PA 1677/007/007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of latest renewal: 01 April 2007

10. DATE OF REVISION OF THE TEXT

July 2024.