SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Mycosat 100,000 I.U/ml Oral Suspension

2. Qualitative and quantitative composition

Ready mixed oral suspension containing 100,000 International units nystatin per ml.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral suspension.

4. Clinical particulars

4.1 Therapeutic indications

The prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract. The suspension provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

4.2 Posology and method of administration

Posology

Prevention and treatment of oral candidiasis:

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) four times daily is an effective regimen.

Infants (1 month to 2 years):

2 ml (200,000 U) 4 times daily (1 ml for each side of the mouth).

Children (over 2 years) and adults:

4 – 6 ml (400,000 – 600,000 U) 4 times daily (half dose in each side of the mouth). It is recommended to keep the medication in contact with the affected areas as long as possible.

Prevention and treatment of intestinal candidiasis:

Neonates (from birth to 1 month) and infants (1 month to 2 years):

1 – 2 ml four times daily administered with milk or other liquid.

If needed, the dose can be increased, even in the neonates. Treatment should be continued for at least 48 hours after clinical cure and/or normalisation of cultures to avoid a relapse.

Children (over 2 years) and adults:

4 – 6 ml (400,000 – 600,000 U) 4 times daily. The suspension should be retained in the mouth for as long as possible (e.g., several minutes) before swallowing. If needed, the dose can be increased.

Treatment should be continued for at least 48 hours after clinical cure and/or normalisation of cultures to avoid a relapse.

Limited clinical studies in premature and low birth weight infants indicate that 1 mL four times daily is effective.

Older people:

No specific dosage recommendations or precautions.

In the prevention and treatment of candidiasis, the dosage regimen for Mycosat 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(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Mycosat Oral Suspension contains sucrose.

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

This medicinal product contains small amounts of ethanol (alcohol), 0.1%.

Mycosat oral preparations should not be used for treatment of systemic mycoses.

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 fetal 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 fetus.

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. 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. Hypersensitivity and angioedema, including facial oedema have been

reported.

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.

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: 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

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose
Glycerin
Carboxymethyl cellulose Sodium
Sodium phosphate dibasic anhydrous
Sodium saccharin
Methyl paraben
Propyl paraben
Ethanol
Peppermint oil
Orange oil
Highly purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store up to 30°C.

6.5 Nature and contents of container

30 ml amber glass bottle, packed in a cardboard carton with aluminum cap.

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

Amman Pharmaceutical Industries (API).

Jordan / Amman, Sahab, Second King Abdullah II Industrial City.

Tel: +962-6-4023072

Fax: +962-6-4023072

E-mail: info@ammanpharma.com

8. Marketing authorisation number(s)

06202/07343/REN/2020

9. Date of first authorisation/renewal of the authorisation

Jul 24, 2021

10. Date of revision of the text

19/02/2016.