

Nystatin Ready Mix Oral Suspension

Summary of Product Characteristics

1. Name of the medicinal product

Nystatin Ready Mix

2. Qualitative and quantitative composition

Nystatin Ready Mix containing 100,000 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

For the treatment of oral fungal infections.

4.2 Posology and method of administration

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 5 years):

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

Children (over 5 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.

Older people:

No specific dosage recommendations or precautions.

A dropper filled up to the cap contains 1 ml of suspension.

The preparation should be retained in the mouth as long as possible before swallowing. The longer the suspension is kept in contact with the affected area in the mouth, before swallowing, the greater will be its effect.

In the prevention and treatment of candidiasis, the dosage regimen for Nystatin 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

Nystatin Ready Mix contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Nystatin Ready Mix contains sorbitol and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Sucrose may be harmful to the teeth when used for two weeks or more.

Nystatin Ready Mix contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed).

Nystatin 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 foetal harm when administered to a pregnant woman or can affect reproductive capacity, however absorption of nystatin from the gastrointestinal 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. 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 suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

<https://sideeffects.health.gov.il>.

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: D01AA01

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

Sucrose, sorbitol solution 70%, propylene glycol, aluminium hydroxide gel, methyl paraben, cinnamaldehyde, anethole, sodium saccharine, propyl paraben, purified water.

1 ml of Nystatin Ready Mix contains:

500 mg of sucrose

0.06 mg of sodium

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening: 3 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Yellow suspension in a 30 ml glass bottle, with a pipette.

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

Taro Pharmaceutical Industries Ltd.
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8. Marketing authorisation number(s)

123-50-25007-00

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