

1. NAME OF THE MEDICINAL PRODUCT

MYSTATIN SUSPENSION (Nystatin Oral Suspension BP 100000 IU/ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Each ml Contains:

Nystatin BP 1,00,000 Units

Approved colour Used

3. PHARMACEUTICAL FORM

Oral Suspension

4. Clinical particulars

4.1 Therapeutic indications

Indications

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

4.2 Posology and method of administration

Posology

Oral Candidiasis

Infants (1 month to 2 years)

1ml should be dropped into the mouth four times a day.

Children (≥ 2 years) and adults

For the treatment of denture sores, and oral infections in children (≥ 2 years) and adults caused by candida 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.

Intestinal candidiasis

Infants (1 month to 2 years)

1ml should be dropped into the mouth four times a day.

Adults

For the treatment of intestinal candidosis 5ml of the suspension should be dropped into the mouth four times daily.

Paediatric population (≥ 2 years)

1ml should be dropped into the mouth four times a day.

For prophylaxis a total daily dosage of 1 million units has been found to suppress the overgrowth of candida albicans in patients receiving broad-spectrum antibiotic therapy.

For prophylaxis in the newborn the suggested dose is 1ml once daily.

The longer the suspension is kept in contact with the affected area in the mouth before swallowing, the greater will be its effect.

Administration should be continued for 48 hours after clinical cure to prevent relapse.

Older people

No specific dosage recommendations or precautions.

4.3 Contraindications

Contraindicated in patients with a history of hypersensitivity to the active substance (s) or to any of the excipients.

4.4 Special warnings and precautions for use

Nystatin Oral Suspension BP contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This should also be taken into account in patients with diabetes mellitus.

Nystatin Oral Suspension contains 0.3 mmol (or 1.3 mg) sodium per 1 ml dose. To be taken into consideration by patients on a controlled sodium diet.

Nystatin Oral Suspension contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm. Nystatin Oral Suspension contains propyl p-hydroxybenzoate and methyl p-hydroxybenzoate 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

No interaction studies have been performed

4.6 Pregnancy and Lactation

Pregnancy

Animal reproductive studies have not been conducted with nystatin.

It is not known whether nystatin can cause foetal harm when taken by 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.

Breastfeeding

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 breast-feeding mothers.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Nystatin is generally well tolerated by all age groups, even during prolonged use. If irritation or sensitization 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.

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 Pharmacodynamics properties

Nystatin is a mixture of antifungal polyenes produced by the growth of certain strains of *Streptomyces noursei*, or by any other means. It consists largely of Nystatin A1.

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

5.2 Pharmacokinetic properties

Nystatin is a tetraene macrolide. There is no data available on the pharmacokinetics as it is not absorbed from the gastro-intestinal tract, skin or vagina and most of the use is topical. Microbial growth-inhibiting concentrations have been shown to be in the range 3-6mg/l.

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

Nystatin BP
Methyl Paraben BP
Propyl Paraben BP
Sodium Saccharine BP
Sodium Metabisulphite BP
Sodium Carboxy Methyl Cellulose BP
Carboxy methyl cellulose Sodium paste BP
Propylene Glycol BP
Sorbitol Solution 70% BP
Sucrose BP
Citric Acid BP
Sodium Citrate BP
Colour Sunset yellow IH
Flavour Orange Oil BP
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

30ml Amber colored Glass bottle along with a dropper.

6.6 Special precautions for disposal

None.

7. APPLICANT/MANUFACTURER

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