Name of the medicinal product

Nystatin Oral Suspension BP

2. Qualitative and quantitative composition

Each ml contains 500,000 I.U. nystatin.

Excipient(s) with known effect:

Also contains 0.2g sucrose; 0.3 mmol (1.3mg) sodium; 0.046 %w/w propyl p-hydroxybenzoate; 0.18% w/w methyl p-hydroxybenzoate and 0.091 %w/w sodium metabisulphite.

For the full list of excipients, see section 6.1.

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 *candidas 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 candidas 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.

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 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 (E223) 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 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 possible risks involved.

Breastfeeding

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 breast-feeding woman.

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 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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard.

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 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 A_1.

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

Corn Starch USP

Lactose monohydrateUSP

Methylparaben sodium USP

Propyl paraben sodium USP

Povidone USP

Purified water USP

Colloidal Silicon DioxideUSP

Magnesium Stearate USP

Talc USP

Methylene chloride USP

Isopropyl Alcohol USP

Polyethylene Glycol USP

Hypromellose USP

Methylparaben USP

Propylparaben USP

Colour Titanium Dioxide USP

Colour Iron Oxide Red Lake

Colour Ponceau 4R Lake

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30ºC. Protect from light.

6.5 Nature and contents of container

Brown colored, round shaped, biconvex, film coated tablet having both sides plain packed in blister strip.

6.6 Special precautions for disposal and other handling

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

requirements.

7. Marketing authorization holder

Emzor Pharmaceutical Industries Limited

No 10 Kolawole Shonibare Street , Ajao Estate, Lagos