

PLEASE READ CAREFULLY

Tystatin Oral Suspension

CONTENT

Each ml contains **100,000 units of nystatin**, methyl paraben 1.8mg & propyl paraben 0.2mg as preservatives and the following inactive ingredients: polyethylene glycol 1500, microcrystalline cellulose, carboxymethylcellulose sodium, saccharin sodium, glycerin, polysorbate 80, raspberry essence and vanilla flavour.

DESCRIPTION

A yellow suspension with a raspberry-vanilla flavour.

INDICATION

Tystatin Oral Suspension is indicated for the treatment of candidal infection of the oral cavity.

RECOMMENDED DOSAGE

Infants:

One ml (equivalent to 100,000 units) four times daily after food. Limited clinical studies in premature and low birth weight infants indicate that 1ml 4 times daily is effective.

Children and Adults:

One to six ml (100,000 to 600,000 units) four times daily after food.

MODE OF ADMINISTRATION

The suspension should be swished throughout or be retained in the mouth for as long as possible before swallowing. Patients should avoid taking food or drink earlier than one hour after a dose. In infants and young children, apply one half of dose in each side of mouth. The dosage should be continued for 48 hours after lesions have resolved.

CONTRAINDICATIONS

Tystatin Oral Suspension is contraindicated in patients with a history of hypersensitivity to the drug or any ingredient in the formulation.

WARNING AND PRECAUTIONS

- **Tystatin Oral Suspension** is not to be used for the treatment of systemic mycoses. Discontinue treatment if sensitization or irritation is reported during use.
- Carcinogenesis, mutagenesis, impairment of fertility- No long-term animal studies have been performed to evaluate carcinogenic potential. There also have been no studies to determine mutagenicity or whether this medication affects fertility in males or females.

INTERACTIONS WITH OTHER MEDICAMENTS

None known

PREGNANCY AND LACTATION

It is not known whether **Tystatin Oral Suspension** can cause foetal harm if administered to pregnant women. It is also not known whether **Tystatin Oral Suspension** is excreted in breast milk. **Tystatin Oral Suspension** should be prescribed for pregnant woman only if the potential benefit to the mother outweighs the potential risk to the foetus. Caution should be exercised when **Tystatin Oral Suspension** is prescribed for a nursing mother.

SIDE EFFECTS

Tystatin Oral Suspension is well tolerated even with prolonged therapy. Oral irritation and sensitization have been reported.

- Gastrointestinal: Diarrhoea (including one case of bloody diarrhoea), nausea, vomiting, gastrointestinal upset/disturbances.
- Dermatologic: Rash, including urticaria has been reported rarely. Stevens-Johnson syndrome has been reported very rarely.
- Other: Tachycardia, bronchospasm, facial swelling, and nonspecific myalgia have also been reported.

SYMPTOMS AND TREATMENT OF OVERDOSE

Since the absorption of nystatin from the gastrointestinal tract is negligible, overdosage causes no systemic toxicity. However, oral doses exceeding 5 million units daily may cause nausea and gastrointestinal upset, and treatment should be symptomatic.

PHARMACODYNAMICS

Nystatin is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. *Candida albicans* demonstrates no significant resistance to nystatin *in vitro* on repeated subculture in increasing levels of nystatin; other *Candida* species become quite resistant. Generally, resistance does not develop *in vivo*. Nystatin acts by binding to sterols in the cell membrane of susceptible *Candida* species with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

PHARMACOKINETICS

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. In patients with renal insufficiency receiving oral therapy with conventional dosage forms, significant plasma concentrations of nystatin may occasionally occur.

PACKING / PACK SIZES

Bottle of 12ml, 30ml and 60ml.

STORAGE CONDITION & USER INSTRUCTIONS

Store below 30°C in well-closed container.

Do not freeze. Protect from light.

Shake well before use.

Keep out of reach of children.

Jauhi daripada kanak-kanak.

Shelf life: please refer to the outer box label.

Manufactured by:

T.O CHEMICALS (1979) LTD.

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