

## Composition

Each ml contains Nystatin 100,000 I.U.

#### **Action**

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. Nystatin is an antibiotic with antifungal activity against a wide variety of yeasts and yeast-like fungi. The antifungal activity of nystatin is at least in part dependent on its binding to a sterol moiety, primarily ergosterol, present in the membrane of sensitive fungi, which results in an increase in the permeability of the membrane and leakage of intra-cellular components. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

#### Indications

- Treatment of infections caused by sensitive strains of *Candida albicans* (Monilia), and specifically for the treatment of monilial infections of the oral cavity and in intestinal moniliasis.
- Candistan Ready Mix suspension is particularly useful for the treatment of thrush in the newborn and monilial infections of the oral cavity and esophagus in infants, children and adults.

### **Contraindications**

Known hypersensitivity to Nystatin.

### Warnings

## **Pregnancy**

Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

#### **Adverse Reactions**

Nystatin is virtually non-toxic and non-sensitizing, and is well tolerated by all age groups, including debilitated infants.

Large oral doses of Nystatin (exceeding 4-5 million units) have occasionally produced diarrhea, gastrointestinal distress, nausea and vomiting.

## **Dosage and Administration**

When administered concomitantly with an antibacterial agent, treatment with Candistan should be continued for as long as the antibacterial agent is given.

Treatment should be continued for at least 48 hours after clinical cure has been achieved, to prevent relapse.

If required, treatment with topical Nystatin may be added to oral Nystatin.

The suspension is intended primarily for pediatric use, but is also suitable for adults. The preparation should be retained in the mouth for as long as possible before swallowing. The mark on the dropper corresponds to 1 ml.

#### **Infants**

The usual dosage is 2 ml 4 times daily, dropped into the mouth or mixed with milk, honey or other non-acid vehicles (half a dose in each side of the mouth).

#### **Neonates**

For prophylaxis, in cases where infection may occur during delivery, the suggested dosage is 1 ml once daily, by dropping directly into the mouth.

# **Children and Adults**

The usual dosage is 4-6 ml 4 times daily, dropped into the mouth. Treatment should be continued for at least 48 hours following clinical cure, to prevent relapse.

# Presentation

Dropper bottle of 12 ml.