NYSTATIN- nystatin suspension
Precision Dose, Inc.

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NYSTATIN ORAL SUSPENSION, USP
(100,000 units per mL)
Rx Only

DESCRIPTION
Nystatin is an antimycotic polyene antibiotic obtained from Streptomyces noursei. Structural formula:

![Structural formula image]

C$_{47}$H$_{75}$NO$_{17}$  MW 926.13

Nystatin Oral Suspension, for oral administration, contains 100,000 USP Nystatin Units per mL.
Inactive ingredients: alcohol (≤ 1% v/v), artificial wild cherry flavor, banana flavor, D&C yellow # 10, FD&C red # 40, glycerin, USP, magnesium aluminum silicate, methylparaben, NF, potassium phosphate dibasic, USP, propylene glycol, USP, propylparaben, NF, purified water, USP and sucrose 33.5%. May also contain citric acid, USP for pH adjustment.

CLINICAL PHARMACOLOGY

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.

Microbiology
Nystatin is both fungicidal and fungistatic 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.

INDICATIONS AND USAGE
Nystatin Oral Suspension is indicated for the treatment of candidiasis in the oral cavity.

CONTRAINDICATIONS
The preparation is contraindicated in patients with a history of hypersensitivity to any of its components.

**PRECAUTIONS**

**General**

This medication 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.

**Pregnancy**

Teratogenic Effects Category C

Animal reproduction studies have not been conducted with nystatin oral suspension. It is also not known whether nystatin oral suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin oral suspension should be given to a pregnant woman only if clearly needed.

**Nursing Mothers**

It is not known whether nystatin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when nystatin is administered to a nursing woman.

**Pediatric Use**

See DOSAGE AND ADMINISTRATION.

**ADVERSE REACTIONS**

Nystatin is well tolerated even with prolonged therapy. Oral irritation and sensitization have been reported. (See PRECAUTIONS: General).

*Gastrointestinal:* Diarrhea (including one case of bloody diarrhea), nausea, vomiting, gastrointestinal upset/disturbances.

*Dermatologic:* Rash, including urticaria has been reported very rarely. Stevens-Johnson syndrome has been reported very rarely.

*Other:* Tachycardia, bronchospasm, facial swelling, and non-specific myalgia have also been rarely reported.

**OVERDOSAGE**

Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset. There have been no reports of serious toxic effects of superinfections (see CLINICAL PHARMACOLOGY, Pharmacokinetics).

**DOSAGE AND ADMINISTRATION**

**INFANTS**
2 mL (200,000 units) four times daily (in infants and young children, use dropper to place one-half of dose in each side of mouth and avoid feeding for 5 to 10 minutes).

NOTE: Limited clinical studies in premature and low birth weight infants indicate that 1 mL four times daily is effective.

CHILDREN AND ADULTS
4-6 mL (400,000 to 600,000 units) four times daily (one-half of dose in each side of mouth). The preparation should be retained in the mouth as long as possible before swallowing.

Continue treatment for at least 48 hours after perioral symptoms have disappeared and cultures demonstrate eradication of *Candida albicans*.

**HOW SUPPLIED**

Nystatin Oral Suspension, USP, 100,000 USP Nystatin Units per mL, is available as a fruit flavored, light creamy yellow, ready-to-use suspension.

- NDC 68094-599-58
- 5 mL per unit dose syringe
- Fifty (50) syringes per shipper

- NDC 68094-599-61
- 5 mL per unit dose cup
- One hundred (100) cups per shipper

- NDC 68094-599-62
- 5 mL per unit dose cup
- Thirty (30) cups per shipper

**SHAKE CUPS WELL BEFORE USING**

**STORAGE**

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid freezing.

Rx Only

**Manufactured By:**
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

**Manufactured For:**
Wockhardt USA, LLC.
Parsippany, NJ 07054

**Packaged By:**
Precision Dose, Inc.
S. Beloit, IL 61080

LI825
Rev. 07/10

**PRINCIPAL DISPLAY PANEL - 5 mL Cup Label**

NDC 68094-599-59

PrecisionDose™
NYSTATIN
NYSTATIN
nystatin suspension

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:68094-599(NDC:60432-537)
Route of Administration: ORAL

Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>Nystatin (UNII: BDF1O1C72E) (Nystatin - UNII:BDF1O1C72E)</td>
<td>Nystatin</td>
<td>500000 [USPU] in 5 mL</td>
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Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>D&amp;C yellow no. 10 (UNII: 35SW5USQ3G)</td>
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<tr>
<td>FD&amp;C red no. 40 (UNII: WZB9127XOA)</td>
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<td>glycerin (UNII: PDC6A3C0O0X)</td>
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<td>potassium phosphate, dibasic (UNII: C77S98N1Z)</td>
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<tr>
<td>propylene glycol (UNII: 6DC9Q167V3)</td>
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propylparaben (UNII: Z8IX2SC1OH)
water (UNII: 059QF0KO0R)
sucrose (UNII: C151H8M554)

Product Characteristics
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Packaging

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<tr>
<td>1</td>
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<td>10 in 1 TRAY</td>
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<td>1</td>
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<tr>
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<td>10 in 1 TRAY</td>
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<td>2</td>
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<td>3</td>
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<td>10 in 1 BAG</td>
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<td>3</td>
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Marketing Information

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Labeler - Precision Dose, Inc. (035886746)

Revised: 2/2012