

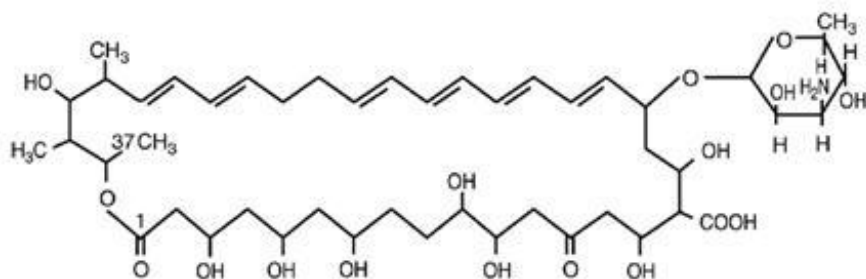
**NYSTATIN- nystatin suspension**  
**Precision Dose, Inc.**

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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:



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 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.

**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**

Oral Suspension, USP  
500,000 units per 5 mL

Pkg: Precision Dose, Inc., S. Beloit, IL 61080



## NYSTATIN

nystatin suspension

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Nystatin (UNII: BDF1O1C72E) (Nystatin - UNII:BDF1O1C72E)	Nystatin	500000 [USPU] in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
alcohol (UNII: 3K9958V90M)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
FD&C red no. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	
methylparaben (UNII: A218C7H9T)	
potassium phosphate, dibasic (UNII: CI71S98N1Z)	
propylene glycol (UNII: 6DC9Q167V3)	

<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>water</b> (UNII: 059QF0K00R)	
<b>sucrose</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	YELLOW	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-599-62	3 in 1 CASE		
1		10 in 1 TRAY		
1	NDC:68094-599-59	5 mL in 1 CUP, UNIT-DOSE		
2	NDC:68094-599-61	10 in 1 CASE		
2		10 in 1 TRAY		
2	NDC:68094-599-59	5 mL in 1 CUP, UNIT-DOSE		
3	NDC:68094-599-58	5 in 1 CASE		
3		10 in 1 BAG		
3		5 mL in 1 SYRINGE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062512	12/15/2005	

**Labeler** - Precision Dose, Inc. (035886746)