



*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 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 to 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 in a cherry, peppermint flavored, light creamy yellow, ready-to-use suspension, supplied in the following oral dosage forms:

NDC 0904-7276-41: 5 mL unit dose cup

NDC 0904-7276-92: Case contains 50 unit dose cups of 5 mL, packaged in 5 trays of 10 unit dose cups each

NDC 0904-7276-70: Case contains 100 unit dose cups of 5 mL, packaged in 10 trays of 10 unit dose cups each

## **Storage**

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

**Distributed by:**  
**MAJOR<sup>®</sup> PHARMACEUTICALS**  
Indianapolis, IN 46268

R06/22

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

Major<sup>®</sup>

NDC 0904-7276-41

Nystatin  
Oral Suspension, USP

500,000 units / 5 mL

Alcohol  $\leq$  1% v/v SHAKE WELL

Delivers 5 mL • See insert  
For Institutional Use Only • Rx Only

MAJOR<sup>®</sup> PHARMACEUTICALS  
Indianapolis, IN 46268

F0868C050624



**NYSTATIN**

nystatin suspension

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0904-7276
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NYSTATIN</b> (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)	NYSTATIN	100000 [USP'U] in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>DIBASIC POTASSIUM PHOSPHATE</b> (UNII: CI71S98N1Z)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCROSE</b> (UNII: C151H8M554)	

## Product Characteristics

<b>Color</b>	yellow (light-creamy)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (with peppermint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0904-7276-92	5 in 1 CASE	11/28/2022	
1		10 in 1 TRAY		
1	NDC:0904-7276-41	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0904-7276-70	10 in 1 CASE	11/28/2022	
2		10 in 1 TRAY		
2	NDC:0904-7276-41	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203621	07/17/2020	

**Labeler** - Major Pharmaceuticals (191427277)

**Registrant** - PAI Holdings, LLC (044940096)

Revised: 2/2026

Major Pharmaceuticals