

**NYSTATIN- nystatin suspension**  
**PAI Holdings, LLC dba PAI Pharma**

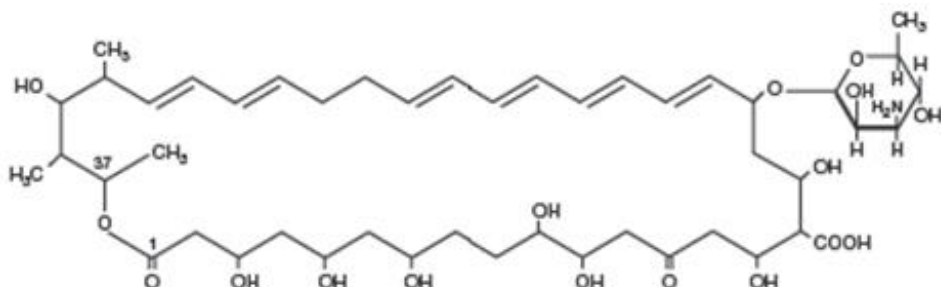
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**Nystatin Oral Suspension USP**  
**[100,000 units per mL]**

**Rx only**

**DESCRIPTION**

Nystatin is an antimycotic polyene antibiotic obtained from *Streptomyces noursei*.

Structural formula:



C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub> MW 926.13

Nystatin Oral Suspension USP, for oral administration, contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol ( $\leq 1\%$  v/v), cherry flavor, citric acid, D&C Yellow No. 10, FD&C Red No. 40, glycerin, magnesium aluminum silicate, methylparaben, potassium phosphate dibasic, propylene glycol, propylparaben, purified water and sucrose.

**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

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.

**To report SUSPECTED ADVERSE REACTIONS, contact PAI Pharma at 1-800-845-8210 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

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

NDC 0121-1045-02: 2 fl oz (60 mL) bottle with calibrated dropper

NDC 0121-1045-16: 16 fl oz (473 mL) bottle

NDC 0121-4045-05: 5 mL unit dose cup. Case contains 40 unit dose cups of 5 mL (NDC 0121-4045-40) packaged in 4 trays of 10 unit dose cups each, 50 unit dose cups of 5 mL (NDC 0121-4045-50) packaged in 5 trays of 10 unit dose cups each and 100 unit dose cups of 5 mL (NDC 0121-4045-00) 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.

**MANUFACTURED BY**  
**PAI Pharma**  
**Greenville, SC 29605**  
**www.paipharma.com**

**R06/24**

**PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

**NDC 0121-1045-16**

**Nystatin Oral Suspension, USP**

**100,000 units per mL**

**SHAKE WELL BEFORE USING**

**Cherry Flavored**

**Rx only**

**16 fl oz (473 mL)**

PAI Pharma  
Greenville, SC 29605

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

**AVOID FREEZING**

Dispense in a tight, light-resistant container as defined in the USP/NF.

X1045160624 R06/24

NDC 0121-1045-16

**Nystatin Oral Suspension, USP**

**100,000 units per mL**

**SHAKE WELL BEFORE USING**

Cherry Flavored

Rx only

16 fl oz (473 mL)


**PAI Pharma**  
Greenville, SC 29605

**Each mL contains:** 100,000 units Nystatin, USP with the following inactive ingredients: alcohol (≤ 1% v/v), cherry flavor, citric acid, D&C Yellow No. 10, FD&C Red No. 40, glycerin, magnesium aluminum silicate, methylparaben, potassium phosphate dibasic, propylene glycol, propylparaben, purified water and sucrose.

**USUAL DOSAGE:** For 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).

**USUAL DOSAGE:** For Children and Adults: See Package Insert.

**WARNINGS: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.** In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.



**NYSTATIN**

nystatin suspension

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0121-1045
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1045-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2024	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA203621	06/21/2024	

**Labeler** - PAI Holdings, LLC dba PAI Pharma (044940096)

## Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	analysis(0121-1045) , label(0121-1045) , manufacture(0121-1045) , pack(0121-1045)

Revised: 7/2024

PAI Holdings, LLC dba PAI Pharma