

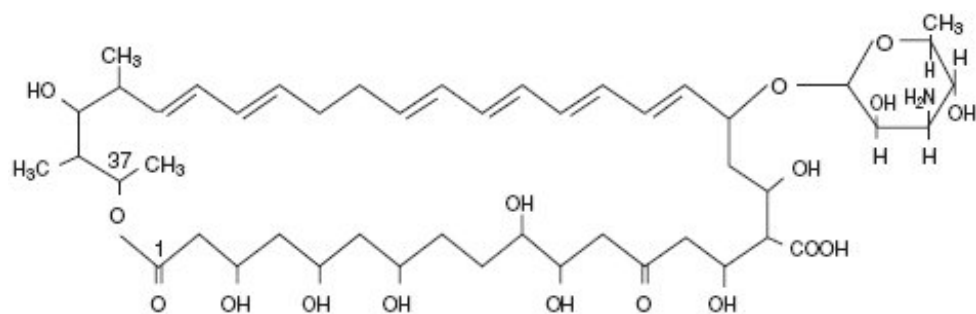
**NYSTATIN- nystatin suspension**  
**A-S Medication Solutions**

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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:



$C_{47}H_{75}NO_{17}$

MW = 926.13

Nystatin Oral Suspension is a cherry-mint flavored suspension for oral administration. It contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol ( $\leq 1\%$  v/v), carboxymethylcellulose sodium, flavor, glycerin, methylparaben, propylparaben, purified water, saccharin sodium, sodium citrate, and sucrose (50% w/v). May also contain citric acid 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 rarely. Stevens-Johnson syndrome has been reported very rarely.

*Other:* Tachycardia, bronchospasm, facial swelling, and nonspecific myalgia have also been 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 or 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

Product: 50090-0217

NDC: 50090-0217-0 60 mL in a BOTTLE, DROPPER

Manufactured for:

**QUALITEST PHARMACEUTICALS**

Huntsville, AL 35811

8083097


R2/15-R1

**Nys tatin**

**NDC 50090–0217–0**  
A–S Medication Solutions, LLC  
**Product No. 1018–0**  
**LOT**  
**NYSTATIN**  
**ORAL SUSPENSION,**  
**USP**  
**100,000 UNITS/ML**  
EACH ML CONTAINS  
100,000 USP NYSTATIN UNITS  
STORE AT 68–77 DEGREES F  
AVOID FREEZING  
**60 ML SUSPENSION**

**DISTRIBUTED BY:**  
A–S Medication Solutions  
Libertyville, IL 60048  
**SOURCE NDC:**  
**0603–1481–49**

**MFG: QUALITEST PHARMACEUTICAL**  
**HUNTSVILLE, AL 35811**  
**RX ONLY – SN#**  
**DOSAGE: SEE PACKAGE INSERT**  
**DISCARD AFTER:**



## NYSTATIN

nystatin suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50090-0217(NDC:0603-1481)	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)		NYSTATIN	100000 [USPU] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALCOHOL (UNII: 3K9958V90M)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SUCROSE (UNII: C15IH8M554)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
Product Characteristics				
Color			Score	
Shape			Size	
Flavor	CHERRY (cherry-mint flavored)		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-0217-0	1 in 1 CARTON	06/21/2016	
1		60 mL in 1 BOTTLE, DROPPER ; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA065148		06/28/2005	

**Labeler** - A-S Medication Solutions (830016429)

Establishment			
Name	Address	ID/FEI	Business Operations

A-S Medication Solutions		830016429	RELABEL(50090-0217)
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Revised: 9/2017

A-S Medication Solutions