
Rx Only

[illegible]

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 Pharmaceutical Associates, Inc. at 1-800-845-8210 or FDA at 1-800-FDA-1088 or 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, peppermint flavored, light creamy yellow, ready-to-use suspension, supplied in the following oral dosage form:

5 mL unit dose cups: 100 cups (10 x 10) NDC 60687-800-17

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

DO NOT USE IF SEAL IS BROKEN.

Distributed by:

American Health Packaging
Columbus, OH 43217

I0868C0124
R01/24

Package/Label Display Panel - Cup Lid - 500,000 UNITS/5 ML



Rx Only

NDC 60687- **800**-40

NYSTATIN
ORAL SUSPENSION, USP

500,000 units/5 mL

Alcohol ≤1% v/v **SHAKE WELL**

Delivers 5 mL

Avoid freezing

See package insert for full
prescribing information and storage.

For Institutional Use Only

American Health Packaging
Columbus, OH 43217

F0868C050124

NYSTATIN			
nystatin suspension			
Product Information			
	HUMAN PRESCRIPTION	Item Code	NDC 60687-800/NDC 6124

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60687-800(NDC:0121-0868)	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)		NYSTATIN	100000 [USP'U] in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
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)				
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SUCROSE (UNII: C151H8M554)				
Product Characteristics				
Color	yellow (Light - Creamy)	Score		
Shape		Size		
Flavor	CHERRY (w/Peppermint)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-800-17	10 in 1 CASE	02/26/2024	
1	NDC:60687-800-46	10 in 1 TRAY		
1	NDC:60687-800-40	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	02/26/2024	

Revised: 2/2024

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