

NYSTATIN ORAL SUSPENSION- nystatin oral suspension solution NuCare Pharmaceuticals, Inc.

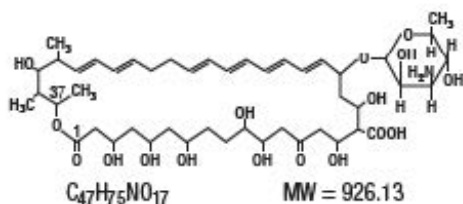
NYSTATIN ORAL SUSPENSION, USP

100,000 units per mL

Rx only

DESCRIPTION

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



Nystatin Oral Suspension 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 non-specific 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

Nystatin Oral Suspension, USP, 100,000 USP Nystatin Units per mL, is available as a cherry-mint flavored, light creamy yellow, ready-to-use suspension in 60 mL bottles with calibrated dropper and 473 mL bottles.

It is supplied as follows:

NDC 68071-2644-6 60 mL

Storage

Store at 20°-25°C (68°-77°F) with excursions permitted between 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]; avoid freezing.

Distributed by:

Lannett Company, Inc.

Philadelphia, PA 19136

L7046

Rev. 09/19

PRINCIPAL DISPLAY PANEL

NDC: 68071-2644-6

Nystatin
60mL Oral Susp.

Each mL contains: 100,000 USP Nystatin Units
See manufacturer's label
for full list of ingredients.

Product #: R0311060
Rx Only

Nystatin

Lot: 00000 NDC: 68071-2644-06
MFR NDC: 0527-5121-62 Exp.: 00-00
Serial# 0000000002

Nystatin

Lot: 00000 NDC: 68071-2644-06
MFR NDC: 0527-5121-62 Exp.: 00-00
Serial# 0000000002



GTIN 00368071264463
Serial# 0000000002
Exp. Date 00-00
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Distributed by: 3 68071 2644 6 3
Lannett Company, Inc. Philadelphia, PA 19136
Packed by:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Rev. 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 68-77°F.

Take _____ teaspoonful(s) every _____ hours _____ times a day.

Patient Instructions

68071264406 60 00000 00000

NYSTATIN ORAL SUSPENSION

nystatin oral suspension solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68071-2644(NDC:0527-5121)
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)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	yellow (light creamy yellow)	Score	
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Shape		Size		
Flavor	CHERRY (cherry-mint flavored)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2644-6	1 in 1 CARTON	02/21/2022	
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 - NuCare Pharmaceuticals,Inc. (010632300)

Establishment			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2644)

Revised: 2/2022

NuCare Pharmaceuticals,Inc.