

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 Xttrium Laboratories, Inc. at 1-800-587-3721 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: 4-6 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 fruit flavored, light creamy yellow, ready-to-use suspension.

60 mL bottle was a calibrated dropper and

1 Pint (473 mL) bottles (0116-4026-16)

Storage

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

Avoid freezing.

Rx Only

Product No.: 4026

Manufactured By:

Xttrium Laboratories, Inc.

1200 E. Business Center Dr.

Mount Prospect, IL 60056

402616BTLLBL
REV. 09-25

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

NDC 0116-4026-16

NYSTATIN ORAL SUSPENSION, USP

(100,000 units per mL)

Each mL contains: 100,000 units Nystatin, USP with the following inactive ingredients: alcohol ($\leq 1\%$ v/v), artificial wild cherry flavor, banana flavor, D&C yellow #10, FD&C red #40, glycerin, USP, magnesium aluminum silicate, methyl paraben, NF, potassium phosphate dibasic, USP, propylene glycol, USP, propylparaben, NF, purified water, USP and sucrose 33.5%.

May also contain citric acid, USP for Ph adjustment.

Fruit Flavored

SHAKE WELL BEFORE USING

Rx Only

NET: 1 Pint (473 mL)

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.

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.

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1200 E. Business Center Dr.

Mount Prospect, IL 60056

402616BTLLBL REV. 09-25

▲ Lift Here

**DO NOT USE IF TAMPER-EVIDENT SEAL IS
BROKEN OR MISSING.**

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NDC 0116-4026-16

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ORAL SUSPENSION, USP
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**Fruit Flavored
SHAKE WELL BEFORE USING**

Rx Only

NET: 1 Pint (473 mL)

PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label

UNIT DOSE

Delivers 5 mL

NDC 0116-4026-05

NYSTATIN

ORAL SUSPENSION, USP

500,000 units / 5 mL

Alcohol \leq 1% v/v SHAKE WELL

Institutional Use Only

Rx Only

Xttrium Laboratories, Inc.

Mount Prospect, IL

SEE INSERT

UNIT DOSE
Delivers 5 mL
NDC 0116-4026-05
NYSTATIN
ORAL SUSPENSION, USP
500,000 units / 5 mL
Alcohol \leq 1% v/v **SHAKE WELL**



301164026050

4026NYS05LID

Institutional Use Only
Rx Only

Xttrium Laboratories, Inc.
Mount Prospect, IL

SEE INSERT

xl[®]

Rx Only

Nystatin
Oral Suspension, USP

Nystatin
Oral Suspension, USP

Rx Only



0116-4026

NYSTATIN- nystatin suspension

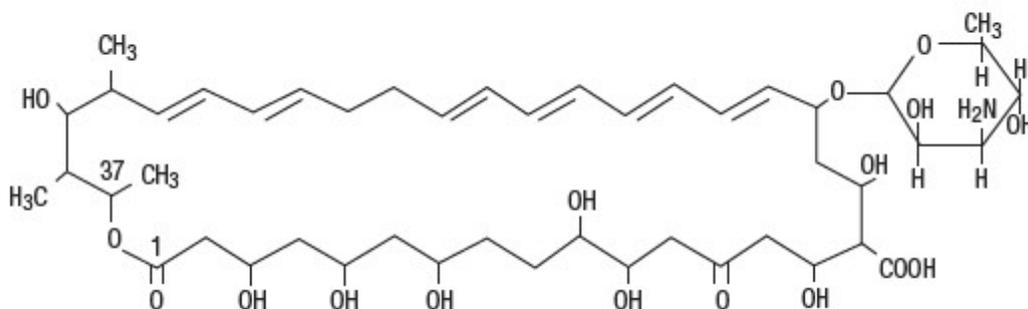
Xttrium Laboratories, Inc.

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, for oral administration, contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol ($\leq 1\%$ v/v), artificial wild cherry flavor, banana flavor, D&C yellow #10, FD&C red #40, glycerin, USP, magnesium aluminum silicate, methylparaben, NF, potassium phosphate dibasic, USP, propylene glycol, USP, propylparaben, NF, purified water, USP and sucrose 33.5%. May also contain citric acid, USP 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.

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Rx Only

Product No.: 4026

Manufactured By:

Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

4026NYSINST
REV. 09-25

NYSTATIN ORAL SUSPENSION

nystatin suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0116-4026
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
SUCROSE (UNII: C151H8M554)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 355W5USQ3G)	
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)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
CHERRY (UNII: BUC5I9595W)	
BANANA (UNII: 4AJZ4765R9)	

Product Characteristics

Color	yellow (Light - Creamy)	Score	
Shape		Size	
Flavor	CHERRY (Banana)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-4026-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/09/2026	
2	NDC:0116-4026-50	5 in 1 CASE	02/09/2026	
2		10 in 1 TRAY		
2	NDC:0116-4026-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0116-4026-11	10 in 1 CASE	02/06/2026	
3		10 in 1 TRAY		
3	NDC:0116-4026-05	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	ANDA062512	02/06/2026	

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	label(0116-4026) , manufacture(0116-4026) , pack(0116-4026)

Revised: 2/2026

Xttrium Laboratories, Inc.