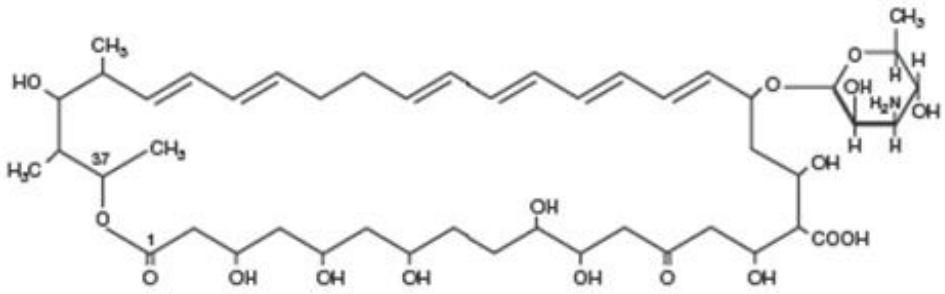
NYSTATIN- nystatin suspension
Pharmaceutical Associates, Inc.

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

Rx Only

DESCRIPTION

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



$C_{47}H_{75}NO_{17}$ MW 926.13

Nystatin Oral Suspension USP, for oral administration, contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol (≤ 1% v/v), artificial peppermint flavor, 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 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 rarely 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 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 forms:

NDC 0121-0810-02: 2 fl oz (60mL) bottle with calibrated dropper

NDC 0121-0810-16: 16 fl oz (473mL) bottle

NDC 0121-4810-05: 5mL unit dose cup

NDC 0121-4810-40: Case contains 40 unit dose cups of 5mL (0121-4810-05) packaged in 4 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.

R10/16

Pharmaceutical Associates, Inc.
Greenville, SC 29605
www.paipharma.com

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

60 mL

NDC 0121-0810-02

Nystatin Oral Suspension, USP

100,000 units per mL

SHAKE WELL BEFORE USING

Packaged with Calibrated Dropper

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

Rx ONLY

Pharmaceutical Associates, Inc.

Greenville, SC 29605

Each mL of cherry, peppermint flavored
oral suspension contains 100,000 units
Nystatin, USP and alcohol (≤ 1% v/v).

USUAL DOSAGE: For Infants: 2 mL(200,000 units) four times daily (in infants andyoung children, use dropper to place one half of dose in each side of the mouth and avoid feeding feeding for 5 to 10 minutes). See insert.

WARNINGS: Keep this and all drugs out of reach of children. In case of accidental overdose, seek professional assistance orcontact a Poison Control Center immediately.

Keep tightly closed. Protect from light.

Store at 20° to 25°C (68° to 77°F)

[See USP Controlled Room Temperature}. AVOID FREEZING

R04/17

X01810020417

PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label

Delivers **5 mL**

NDC 0121-4810-05

N YSTATIN
O RAL
S USPENSION, USP

500,000 units / 5 mL

Alcohol ≤ 1% v/v **SHAKE WELL**

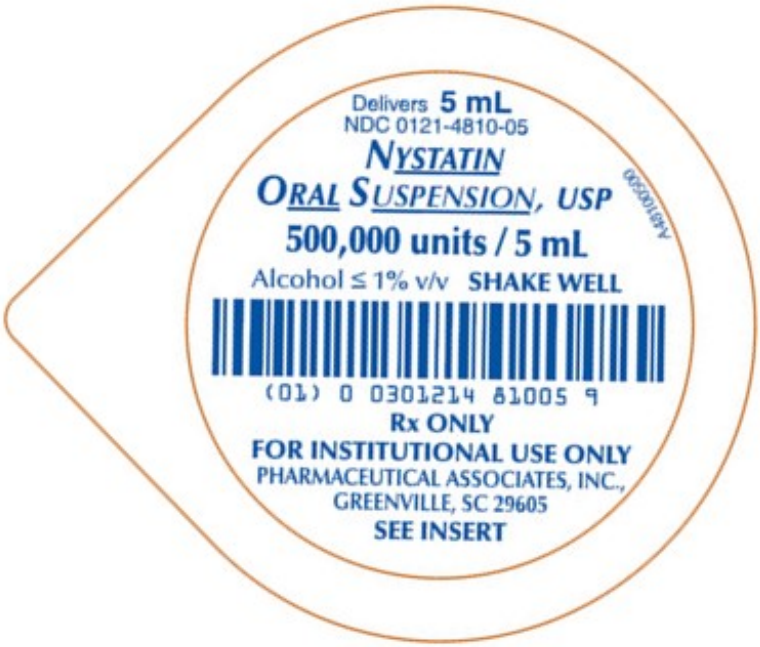
Rx ONLY

FOR INSTITUTIONAL USE ONLY

PHARMACEUTICAL ASSOCIATES, INC.,
GREENVILLE, SC 29605

SEE INSERT

A48100500



NYSTATIN

nystatin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0121-0810
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)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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

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:0121-0810-02	60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/01/2016	
2	NDC:0121-0810-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203621	02/01/2016	

NYSTATIN

nystatin suspension

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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)	

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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:0121-4810-40	4 in 1 CASE	02/01/2016	
1		10 in 1 TRAY		
1	NDC:0121-4810-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-4810-00	10 in 1 CASE	02/01/2016	
2		10 in 1 TRAY		
2		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
3	NDC:0121-4810-50	5 in 1 CASE	06/26/2020	
3		10 in 1 PACKAGE		
3		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	02/01/2016	

Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0810, 0121-4810)