NYSTATIN- nystatin suspension
ATLANTIC BIOLOGICALS CORP.

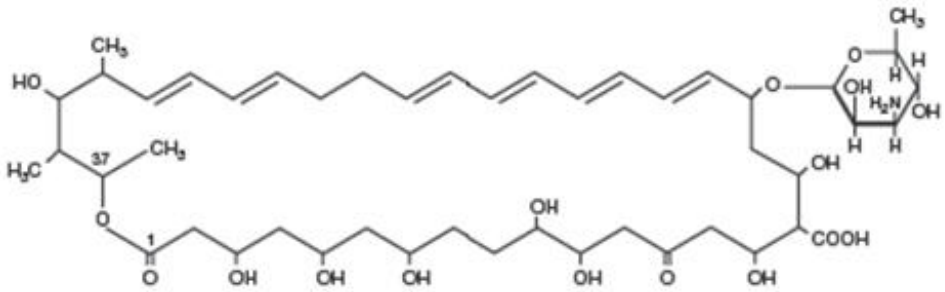
Nystatin Oral Suspension USP
[100,000 units per mL]

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), 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

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 PAI Pharma 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 flavored, light creamy yellow, ready-to-use suspension, supplied in the following oral dosage forms:

NDC 17856-1045-01 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML CUP 72 ct UD
NDC 17856-1045-02 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML CUP 1ct UD
NDC 17856-1045-03 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML SYRINGE 48 ct UD
NDC 17856-1045-04 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML SYRINGE 1ct UD
NDC 17856-1045-05 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML ENFIT SYRINGE 48 ct UD
NDC 17856-1045-06 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML ENFIT SYRINGE 1 ct UD
NDC 17856-1045-07 NYSTATIN ORAL SUSP 100,000 UNITS/ML - 1 ML ENFIT SYRINGE 120 ct UD
NDC 17856-1045-08 NYSTATIN ORAL SUSP 100,000 UNITS/ML - 1 ML ENFIT SYRINGE 1ct UD

NDC 17856-1045-09 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML ENFIT SYRINGE 1ct UD OVERWRAP

Storage

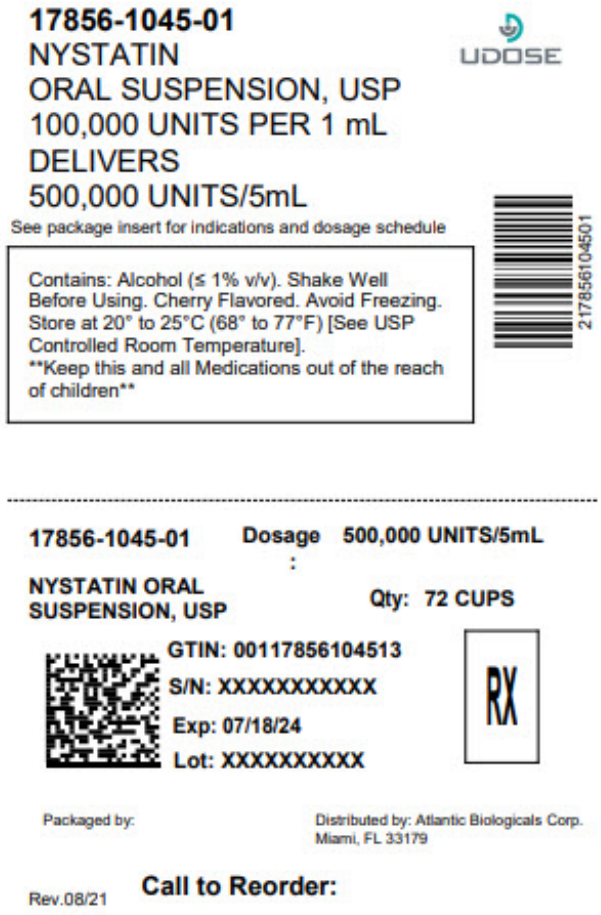
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Avoid freezing.

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

PRINCIPAL DISPLAY PANEL



17856-1045-03
NYSTATIN
ORAL SUSPENSION, USP
100,000 UNITS PER 1 mL
DELIVERS
500,000 UNITS/5mL

UDOSE

See package insert for indications and dosage schedule

Contains: Alcohol (≤ 1% v/v). Shake Well Before Using. Cherry Flavored. Avoid Freezing. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Keep this and all Medications out of the reach of children

217856104503

17856-1045-03 **Dosage :** **500,000 UNITS/5mL**

NYSTATIN ORAL SUSPENSION, USP **Qty: 48 SYRINGES**

GTIN: 00117856104537
S/N: XXXXXXXXXXX
Exp: 07/18/24
Lot: XXXXXXXXXX

RX

Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-1045-07
NYSTATIN
ORAL SUSPENSION, USP
100,000 UNITS PER 1 mL
DELIVERS
100,000 UNITS/1mL

UDOSE

See package insert for indications and dosage schedule

Contains: Alcohol (≤ 1% v/v). Shake Well Before Using. Cherry Flavored. Avoid Freezing. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Keep this and all Medications out of the reach of children

217856104507

17856-1045-07 **Dosage :** **100,000 UNITS/1mL**

NYSTATIN ORAL SUSPENSION, USP **Qty: 120 ENFIT SYRINGES**

GTIN: 00117856104575
S/N: XXXXXXXXXXX
Exp: 07/18/24
Lot: XXXXXXXXXX

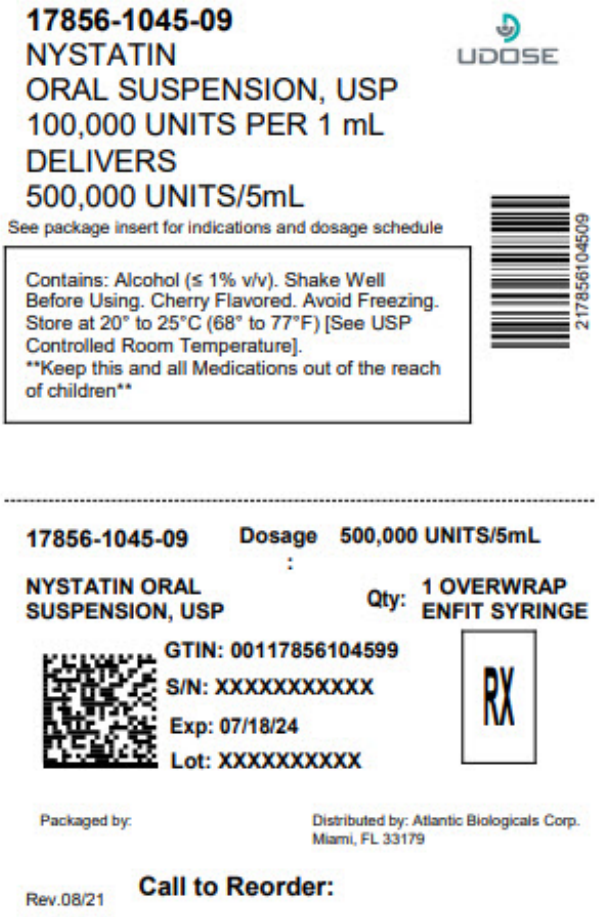
RX

Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:



NYSTATIN

nystatin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17856-1045(NDC:0121-1045)
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)	

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	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-1045-1	72 in 1 BOX, UNIT-DOSE	07/18/2024	
1	NDC:17856-1045-2	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-1045-3	48 in 1 BOX, UNIT-DOSE	07/18/2024	
2	NDC:17856-1045-4	5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:17856-1045-5	48 in 1 BOX, UNIT-DOSE	07/18/2024	
3	NDC:17856-1045-6	5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:17856-1045-7	120 in 1 BOX, UNIT-DOSE	07/18/2024	
4	NDC:17856-1045-8	1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:17856-1045-9	1 in 1 BAG	07/18/2024	
5		5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203621	06/21/2024	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations

ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-1045)

Revised: 7/2024 ATLANTIC BIOLOGICALS CORP.