NYSTATIN- nystatin suspension
ATLANTIC BIOLOGICALS CORP.

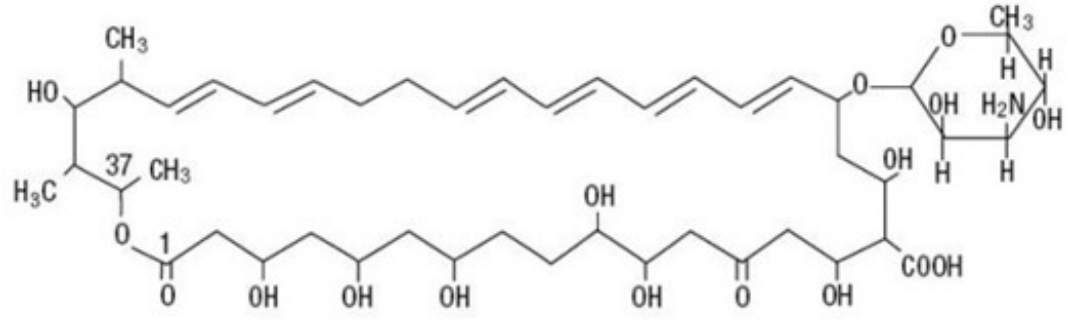
NYSTATIN ORAL
SUSPENSION, USP

(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, for oral administration, contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol (≤ 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.

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: 4–6 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 bottles with a calibrated dropper and 1 Pint (473 mL) bottles.

Storage

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

Rx Only

Product No.: 8537

Manufactured For:
Wockhardt USA, LLC
Parsippany, NJ 07054

Manufactured By:
Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

28537B
REV. 09-09

Distributed by Atlantic Biologicals

Miami, Fl 33179

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

MGP

NDC

17856-0538-06 1 ML ENFIT SYR

17856-0538-07 2 ML ENFIT SYR

17856-0537-08 3 ML ENFIT SYR

17856-0537-09 .5 ML ENFIT SYR

NYSTATIN ORAL
SUSPENSION, USP

(100,000 units
per mL)

Fruit Flavored

Rx Only

NDC 17856-0538-06
NYSTATIN ORAL
SUSPENSION, USP
Rx Only --- SHAKE WELL
100,000 UNITS / 1mL ENFIT Syringe
Fruit Flavored
Delivers 1 mL

PACKAGING INFORMATION:
Dosage per Syringe(s): 1 mL
Syringe(s) per container: 120

See package insert for indications and dosage schedule.

Other Information:
Store at 20°-25°C (68°-77°F) [See USP for Controlled Room Temperature]. Avoid freezing

Shake well before use.

KEEP NYSTATIN AND ALL MEDICINES OUT OF REACH OF CHILDREN.

Mfg by: Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX

17856053806

NDC 17856-0538-07
NYSTATIN ORAL
SUSPENSION, USP
Rx Only --- SHAKE WELL
200,000 UNITS / 2mL ENFIT Syringe
Fruit Flavored
Delivers 2 mL

PACKAGING INFORMATION:
Dosage per Syringe(s): 2 mL
Syringe(s) per container: 120

See package insert for indications and dosage schedule.

Other Information:
Store at 20°-25°C (68°-77°F) [See USP for Controlled Room Temperature]. Avoid freezing

Shake well before use.

KEEP NYSTATIN AND ALL MEDICINES OUT OF REACH OF CHILDREN.

Mfg by: Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
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Miami, FL 33179

Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX

17856053807

NDC 17856-0538-08
NYSTATIN ORAL
SUSPENSION, USP
Rx Only --- SHAKE WELL
300,000 UNITS / 3mL ENFIT Syringe
Fruit Flavored
Delivers 3 mL

DOSAGE:
Dosage per Syringe(s): 3 mL
Syringe(s) per container: 120

See package insert for indications and dosage schedule.

Other Information:
Store at 20°-25°C (68°-77°F) [See USP for Controlled Room Temperature]. Avoid freezing

Shake well before use.

KEEP NYSTATIN AND ALL MEDICINES OUT OF REACH OF CHILDREN.

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Morton Grove, IL 60053

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX

17856053808

NDC 17856-0538-09
NYSTATIN ORAL
SUSPENSION, USP
Rx Only --- SHAKE WELL
50,000 UNITS / 0.5mL ENFIT Syringe
Fruit Flavored
Delivers 0.5 mL

PACKAGING INFORMATION:
Dosage per Syringe(s): 0.5 mL
Syringe(s) per container: 120

See package insert for indications and dosage schedule.

Other Information:
Store at 20°-25°C (68°-77°F) [See USP for Controlled Room Temperature]. Avoid freezing

Shake well before use.

KEEP NYSTATIN AND ALL MEDICINES OUT OF REACH OF CHILDREN.

Mfg by: Morton Grove Pharmaceuticals, Inc.
Morton Grove, IL 60053

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX

17856053809

PRINCIPAL DISPLAY PANEL

MGP

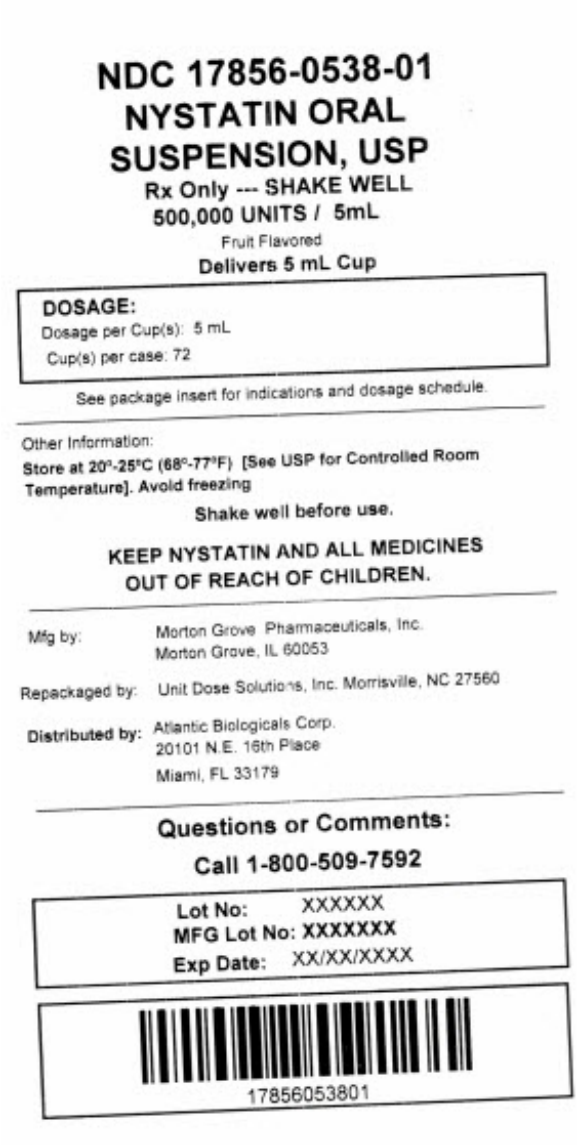
NDC 17856-0538-1

NYSTATIN ORAL

SUSPENSION, USP 5mL CUP 72

Fruit Flavored

RX ONLY



NYSTATIN

nystatin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17856-0538(NDC:60432-537)
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**
water (UNII: 059QF0KO0R)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	

propylene glycol (UNII: 6DC9Q167V3)	
glycerin (UNII: PDC6A3C0OX)	
sucrose (UNII: C151H8M554)	
potassium phosphate, dibasic (UNII: CI71S98N1Z)	
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
FD&C red no. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	YELLOW (Light creamy yellow)	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0538-6	1 mL in 1 SYRINGE; Type 0: Not a Combination Product	10/13/2017	
2	NDC:17856-0538-7	2 mL in 1 SYRINGE; Type 0: Not a Combination Product	10/13/2017	
3	NDC:17856-0538-8	3 mL in 1 SYRINGE; Type 0: Not a Combination Product	10/13/2017	
4	NDC:17856-0538-9	.5 mL in 1 SYRINGE; Type 0: Not a Combination Product	10/13/2017	
5	NDC:17856-0538-5	5 mL in 1 SYRINGE; Type 0: Not a Combination Product	11/10/2017	
6	NDC:17856-0538-1	72 in 1 BOX, UNIT-DOSE	09/25/2018	
6		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	04/15/1995	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0538) , relabel(17856-0538)