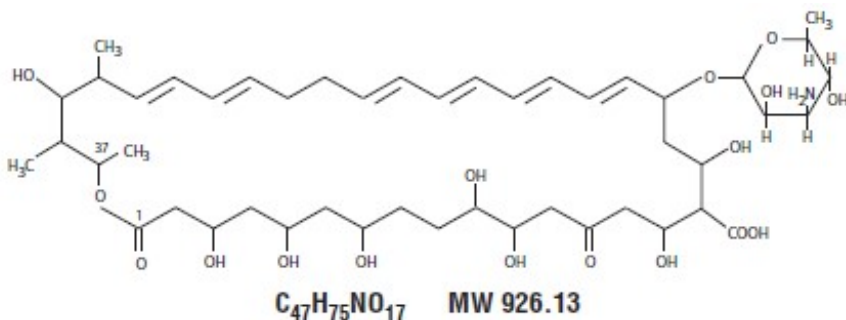


**NYSTATIN- nystatin suspension**  
**ATLANTIC BIOLOGICALS CORP.**

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**NYSTATIN ORAL SUSPENSION, USP**

**DESCRIPTION**

Nystatin is obtained from *Streptomyces noursei*. It is known to be a mixture, but the composition has not been completely elucidated. Nystatin A is closely related to amphotericin B. Each is a macro-cyclic lactone containing a ketal ring, an *all-trans* polyene system, and a mycosamine (3-amino-3-deoxyrhamose) moiety. Structural formula:



Nystatin Oral Suspension, for oral administration, contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol ( $\leq 1\%$  v/v), sucrose 50% w/v, peppermint oil, NF, cinnamaldehyde, disodium hydrogen phosphate, USP, carboxymethylcellulose sodium, USP, glycerin, USP, saccharin sodium, USP, cherry flavor, methylparaben, NF, propylparaben, NF and purified water, USP. May also contain sodium hydroxide, NF and/or hydrochloric acid, NF for pH adjustment.

**CLINICAL PHARMACOLOGY**

Nystatin acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin is absorbed very sparingly following oral administration, with no detectable blood levels when given in the recommended doses.

**INDICATIONS AND USAGE**

Nystatin oral suspension is indicated for the treatment of infections of the oral cavity caused by *Candida albicans*.

**CONTRAINDICATIONS**

Nystatin is contraindicated in patients with a history of hypersensitivity to nystatin or any of the suspension components.

## **PRECAUTIONS**

### **General**

Discontinue treatment with nystatin if sensitization or irritation is reported during use. Nystatin is not effective in the treatment of systemic mycoses since it is not significantly absorbed from the gastrointestinal tract.

### **Information for the Patient**

Patient should be advised to retain nystatin in the mouth as long as possible and to continue its use for at least 2 days after symptoms have subsided.

There should be no interruption or discontinuation of the medication until the prescribed course of treatment is completed, even though symptomatic relief may occur within a few days.

If symptoms of local irritation develop, the physician should be notified immediately.

### **Laboratory Tests**

If there is a lack of therapeutic response, appropriate microbiological studies (e.g., KOH smears and/or cultures) should be repeated to confirm the diagnosis of candidiasis and rule out other pathogens before instituting another course of therapy.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. In mice exposed to nystatin 50 mg/kg by injection, an increased incidence of chromosomal aberrations, consisting primarily of chromatid breaks, was observed in bone marrow cells. However, there have been no studies to determine the mutagenicity of orally-administered nystatin or its effects on fertility in males or females.

### **Pregnancy:**

#### **Teratogenic Effects**

Teratogenicity studies have not been conducted with nystatin. It is also not known whether nystatin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin should be given to a pregnant woman only if clearly needed.

#### **Nonteratogenic Effects**

In one rat reproductive study, nystatin was administered orally to pregnant rats in single doses of 100, 500, or 3000 mg/kg on the ninth day of gestation, or as multiple doses of 500 mg/kg/day on gestation days 1-20, 1-4, 7-10, 11-14, or 15-18. It was found that nystatin had a slight abortive effect when used during the whole period of pregnancy. No abnormalities were seen in surviving fetuses. Although no adverse effects or complications have been attributed to the use of intra-vaginal nystatin in neonates born to women treated during pregnancy, no similar studies evaluating complications of oral nystatin have been conducted.

#### **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** section for pediatric dosing recommendations.

## **ADVERSE REACTIONS**

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 OR LEADING PHARMA, LLC AT 1-844-740-7500 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Gastrointestinal symptoms including diarrhea, gastrointestinal distress, nausea, vomiting and burning of the mouth have been reported. Hypersensitivity reactions including rash, pruritus, and anaphylactoid reaction have also been reported.

## **OVERDOSAGE**

Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset.

## **DOSAGE AND ADMINISTRATION**

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric patients and adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half of dose in each side of mouth).

NOTE: Limited clinical studies in neonates, including premature and low-birth weight neonates, indicate that 1 mL (100,000 units) four times daily is effective.

Local treatment should be continued at least 48 hours after perioral symptoms have disappeared and/or cultures returned to normal. It is recommended that the drug be retained in the mouth as long as possible before swallowing.

## **CAUTION**

The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions

## **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 the following sizes:

NDC 17856-0509-01 NYSTATIN 100,000 UNITS/ML - 2 ML ENFIT SYRINGE 120 ct UD

NDC 17856-0509-03 NYSTATIN 100,000 UNITS/ML - 3 ML ENFIT SYRINGE 120 ct UD

NDC 17856-0509-05 NYSTATIN 100,000 UNITS/ML - 0.5 ML ENFIT SYRINGE 120 ct UD

NDC 17856-0509-07 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML SYRINGE 1 ct UD

NDC 17856-0509-08 NYSTATIN ORAL SUSP 100,000 UNITS/1ML - 5 ML SYRINGE 1 ct UD

## **storage**

This package is child-resistant. Keep out of reach of children. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid freezing

**Rx Only**

**Manufactured by:**

Medley Pharmaceuticals Ltd.

Plot No. 18 and 19, Survey No. 378 / 7 & 8, 379 / 2 & 3,  
Zari Causeway Road, Kachigam, Daman - 396210, INDIA.

**Distributed by:**

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

**17856-0509-01**

**NYSTATIN**

**ORAL SUSPENSION, USP**

**100,000 UNITS PER 1 mL**

**DELIVERS**

**200,000 UNITS/2mL**



See package insert for indications and dosage schedule

Contains: Alcohol  $\leq$  1% v/v. Shake Well Before Using. Cherry-Mint 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\*\*



**17856-0509-01      Dosage    200,000 UNITS/2mL**

**NYSTATIN ORAL  
SUSPENSION, USP**

**Qty:    120 ENFIT  
          SYRINGES**

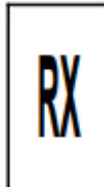


**GTIN: 00117856050919**

**S/N: XXXXXXXXXXXX**

**Exp: 07/17/24**

**Lot: XXXXXXXXXXXX**



Packaged by:

Distributed by: Atlantic Biologicals Corp.  
Miami, FL 33179

Rev.08/21

**Call to Reorder:**

**17856-0509-05**  
**NYSTATIN**  
**ORAL SUSPENSION, USP**  
**100,000 UNITS PER 1 mL**  
**DELIVERS**  
**50,000 UNITS/0.5mL**



See package insert for indications and dosage schedule

Contains: Alcohol  $\leq$  1% v/v. Shake Well Before Using. Cherry-Mint 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\*\***



**17856-0509-05     Dosage   50,000 UNITS/0.5mL**  
 :  
**NYSTATIN ORAL     Qty:   120 ENFIT**  
**SUSPENSION, USP     SYRINGES**



**GTIN: 00117856050957**  
**S/N: XXXXXXXXXXXX**  
**Exp: 07/17/24**  
**Lot: XXXXXXXXXXXX**



Packaged by:

Distributed by: Atlantic Biologicals Corp.  
Miami, FL 33179

Rev.08/21

**Call to Reorder:**

**NYSTATIN**  
nystatin suspension

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:17856-0509(NDC:69315-504)
<b>Route of Administration</b>	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
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>CINNAMALDEHYDE</b> (UNII: SR60A3XG0F)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	

## Product Characteristics

<b>Color</b>	yellow (light creamy yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (cherry-mint flavored)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0509-1	120 in 1 BOX, UNIT-DOSE	07/17/2024	
1	NDC:17856-0509-2	2 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:17856-0509-3	120 in 1 BOX, UNIT-DOSE	07/17/2024	
2	NDC:17856-0509-4	3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:17856-0509-5	120 in 1 BOX, UNIT-DOSE	07/17/2024	
3	NDC:17856-0509-6	0.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:17856-0509-7	1 in 1 BAG	07/17/2024	
4		5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:17856-0509-8	1 in 1 BAG	07/17/2024	
5		5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA214346	12/05/2022	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0509)

Revised: 7/2024

ATLANTIC BIOLOGICALS CORP.