

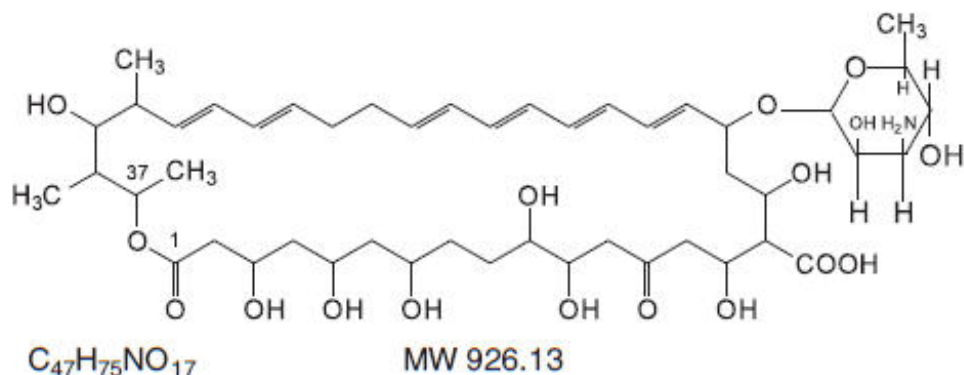
**NYSTATIN- nystatin suspension**  
**VistaPharm, Inc.**

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**NYSTATIN ORAL**  
**SUSPENSION, USP**

**Rx Only**

**DESCRIPTION**

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



Nystatin Oral Suspension, USP, for oral administration contains 100,000 Nystatin units per mL. In addition, the yellow opaque suspension contains the following inactive ingredients : Alcohol (0.5% v/v), USP, Alcohol free Bubble Gum Flavoring, Carboxymethylcellulose Sodium, USP, Dibasic Sodium Phosphate, USP, Glycerin Natural 99.5%, USP, Methylparaben, NF, (Preservative), Monobasic Sodium Phosphate, USP, Propylparaben, NF, (Preservative), Purified Water, USP, Saccharin Sodium, USP, and Sucrose, NF.

**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, USP, 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 nonspecific myalgia have also been rarely reported.

To report SUSPECTED ADVERSE EVENTS, contact FDA at 1-800-FDA-1088 or [www.fda.gov](http://www.fda.gov).

## 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 or 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 Nystatin units per mL, is available as a bubble gum flavored, yellow opaque, ready-to-use suspension.

Nystatin Oral Suspension, USP, is available as follows:

NDC 66689-008-02: 2 fl. oz. bottle (60 mL): supplied in individual carton with calibrated dropper;

NDC 66689-008-08: 8 fl. oz. bottle (237 mL);

NDC 66689-008-16: 16 fl. oz. bottle (480 mL).

### **Storage**

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

AVOID FREEZING

### **Rx Only**

#### **Manufactured By:**

**VistaPharm<sup>®</sup>**

Largo, FL 33771

VP1086R2

06/19

## **PRINCIPAL DISPLAY PANEL - 60 mL Bottle**

NDC 66689-008-02

**NYSTATIN ORAL**

**SUSPENSION, USP**

**100,000 units per mL**

**Contains: Alcohol 0.5% v/v**

(Bubblegum Flavored)

**SHAKE WELL BEFORE USING**

**At The Time Of Dispensing Replace**


**Cap with Safety Cap Dropper**


**2 fl. oz.**

**(60 mL)**

**Rx only**

**VistaPharm®**

<p><b>DO NOT USE IF SEAL UNDER CAP IS MISSING OR APPEARS TO BE BROKEN</b></p> <p><b>Each 1 mL Contains:</b> 100,000 units Nystatin, USP.</p> <p><b>STORAGE:</b> Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. <b>AVOID FREEZING.</b></p> <p>Dispense in a tight, light-resistant container as defined in the USP.</p> <p><b>Manufactured by:</b> VistaPharm, Inc. VP1083R1 Largo, FL 33771, USA 08/18</p>  <p>6668900802</p>	<p>NDC 66689-008-02</p> <p><b>NYSTATIN ORAL SUSPENSION, USP</b></p> <p>100,000 units per mL Contains: Alcohol 0.5% v/v (Bubblegum Flavored)</p> <p><b>SHAKE WELL BEFORE USING</b> <b>At The Time Of Dispensing Replace Cap with Safety Cap Dropper</b></p> <p><b>2 fl. oz. (60 mL)</b></p> <p><b>Rx Only</b> <i>VistaPharm</i></p>	<p><b>USUAL DOSAGE: For Infants:</b> 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).</p> <p><b>For Children and Adults:</b> 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half of dose in each side of the mouth). The preparation should be retained in the mouth as long as possible before swallowing.</p> <p><b>Keep This and All Medications Out of the Reach of Children.</b> In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.</p> <p>RETAIN CARTON FOR ADDITIONAL PRODUCT INFORMATION.</p>	<p>UNVARNISHED AREA FOR LOT NUMBER AND EXP. DATE.</p>
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**THIS SIDE OFF FIRST** 

**PRINCIPAL DISPLAY PANEL - 60 mL Carton**

NDC 66689-008-02

**NYSTATIN ORAL**

**SUSPENSION, USP**

**100,000 units per mL**

(Bubblegum Flavored)

Contains: Alcohol 0.5% v/v

**SHAKE WELL BEFORE USING**

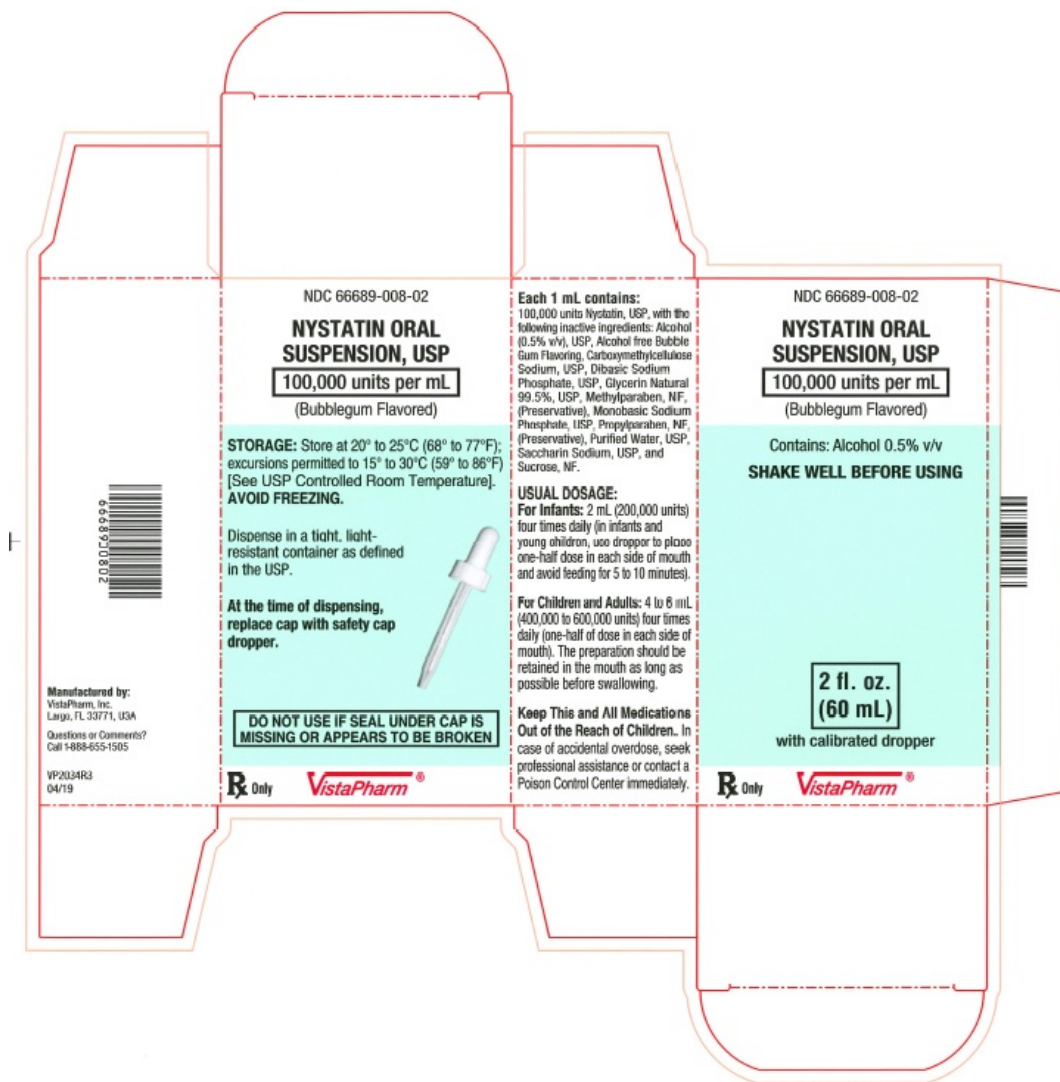
**2 fl. oz.**

**(60 mL)**

**with calibrated dropper**

**Rx only**

**VistaPharm®**



**PRINCIPAL DISPLAY PANEL - 480 mL Bottle**

NDC 66689-008-16

**NYSTATIN ORAL  
SUSPENSION, USP**

**100,000 units per mL**

**Contains: Alcohol 0.5% v/v**  
(Bubblegum Flavored)

**SHAKE WELL BEFORE USING**

**16 fl. oz.**

**(480 mL)**

**Rx only**

**VistaPharm®**

DO NOT USE IF SEAL UNDER CAP IS MISSING  
OR APPEARS TO BE BROKEN

Each 1 mL Contains: 100,000 units Nystatin, USP, with the following inactive ingredients: Alcohol (0.5% v/v), USP, Alcohol free Bubble Gum Flavoring, Carboxymethylcellulose Sodium, USP, Dibasic Sodium Phosphate, USP, Glycerin Natural 99.5%, USP, Methylparaben, NF, (Preservative), Monobasic Sodium Phosphate, USP, Propylparaben, NF, (Preservative), Purified Water, USP, Saccharin Sodium, USP, and Sucrose, NF.

Dispense in a tight, light-resistant container as defined in the USP.



NDC 66689-008-16

# NYSTATIN ORAL SUSPENSION, USP

100,000 units per mL  
Contains: Alcohol 0.5% v/v

(Bubblegum Flavored)

**SHAKE WELL BEFORE USING**

16 fl. oz.  
(480 mL)

Rx Only

**VistaPharm**

**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).

For 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.

**Keep This and All Medications Out of the Reach of Children.** In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

**STORAGE:** Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].  
**AVOID FREEZING**

**Manufactured by:**  
VistaPharm, Inc.  
Largo, FL 33771, USA

VP1085R1  
08/18

UNVARNISHED  
AREA FOR LOT  
NUMBER AND  
EXP. DATE.

## PRINCIPAL DISPLAY PANEL - 480 mL Carton

NDC 66689-008-16

### NYSTATIN ORAL SUSPENSION, USP

100,000 units per mL

(Bubblegum Flavored)

Contains: Alcohol 0.5% v/v

**SHAKE WELL BEFORE USING**

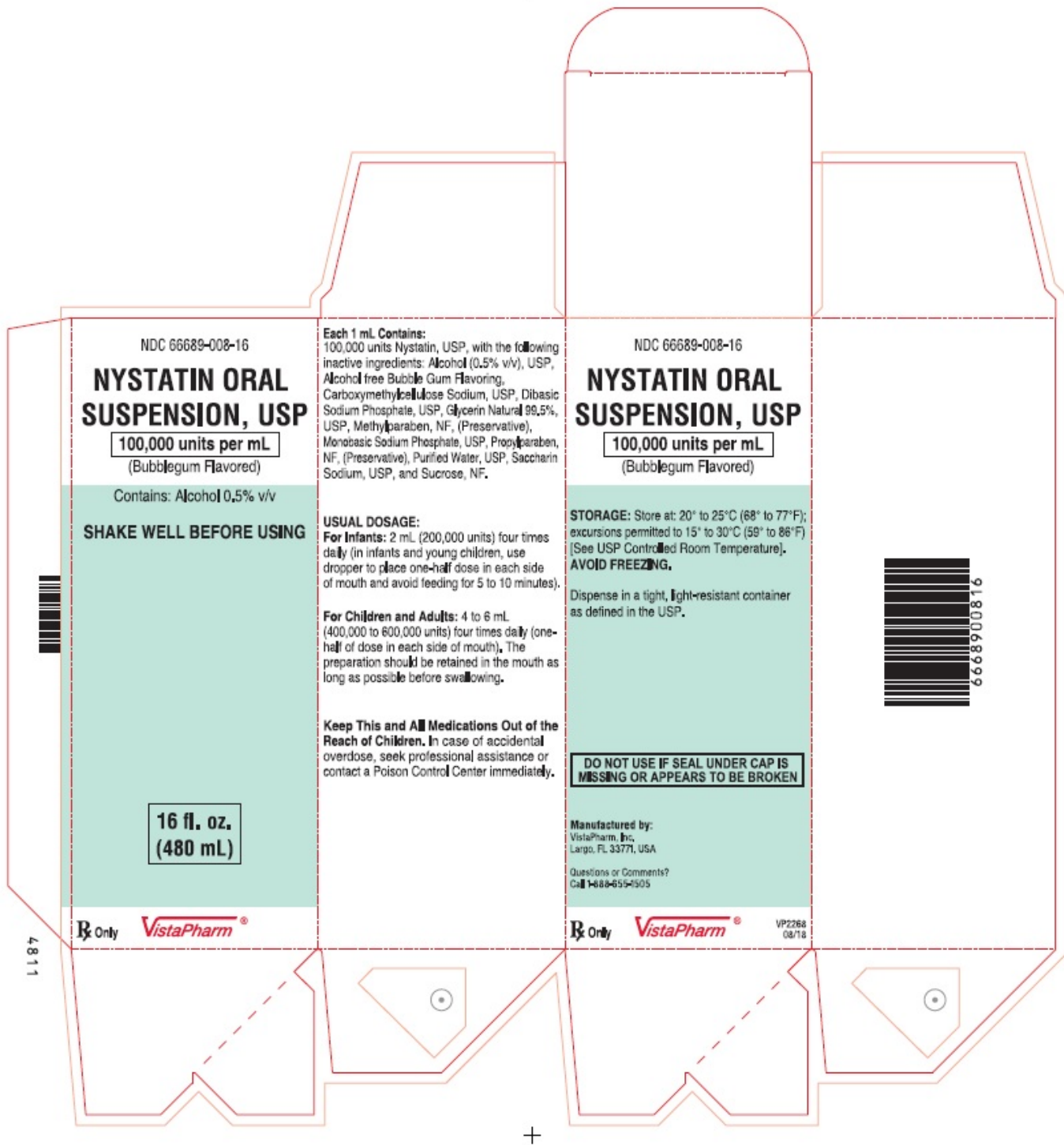
16 fl. oz.

(480 mL)

Rx only

**VistaPharm**<sup>®</sup>





## NYSTATIN

nystatin suspension

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:66689-008
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)	NYSTATIN	100000 [USPU] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	YELLOW (Light yellow)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66689-008-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	
2	NDC:66689-008-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	
3	NDC:66689-008-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065422	05/01/2012	

**Labeler** - VistaPharm, Inc. (116743084)

Revised: 9/2019

VistaPharm, Inc.