

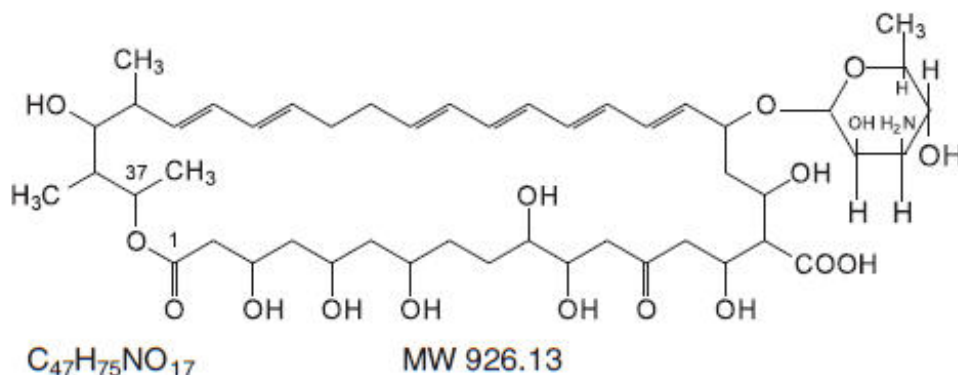
NYSTATIN- nys tatin suspension
VistaPharm, Inc.

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.

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®

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®


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

Each 1 mL Contains:
100,000 units Nystatin, USP.

STORAGE: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
AVOID FREEZING.

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

Manufactured by:
VistaPharm, Inc. VP1083R1
Largo, FL 33771, USA 08/18



6668900802

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®**

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 the 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.

RETAIN CARTON FOR ADDITIONAL PRODUCT INFORMATION.

UNVARNISHED
AREA FOR LOT
NUMBER AND
EXP. DATE.

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

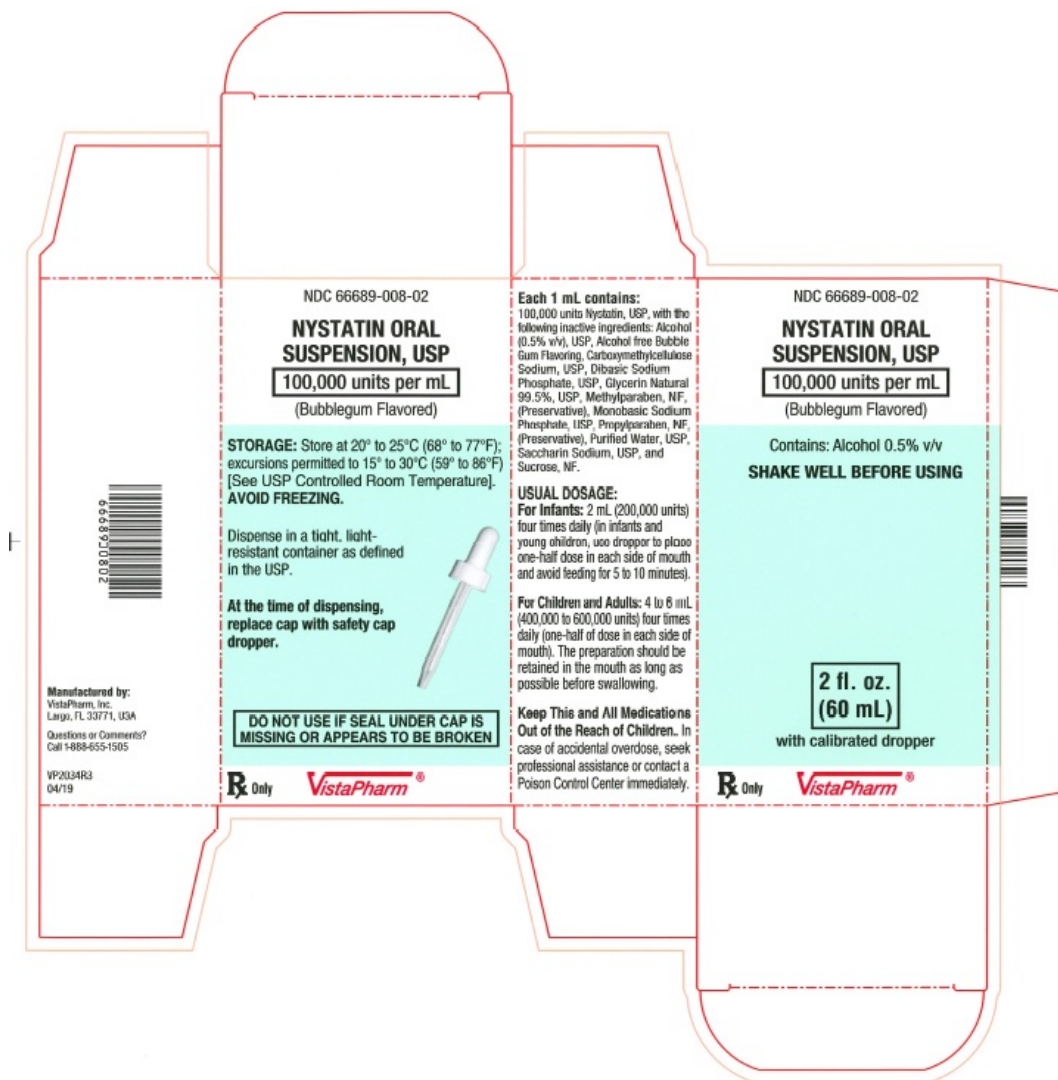
2 fl. oz.

(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

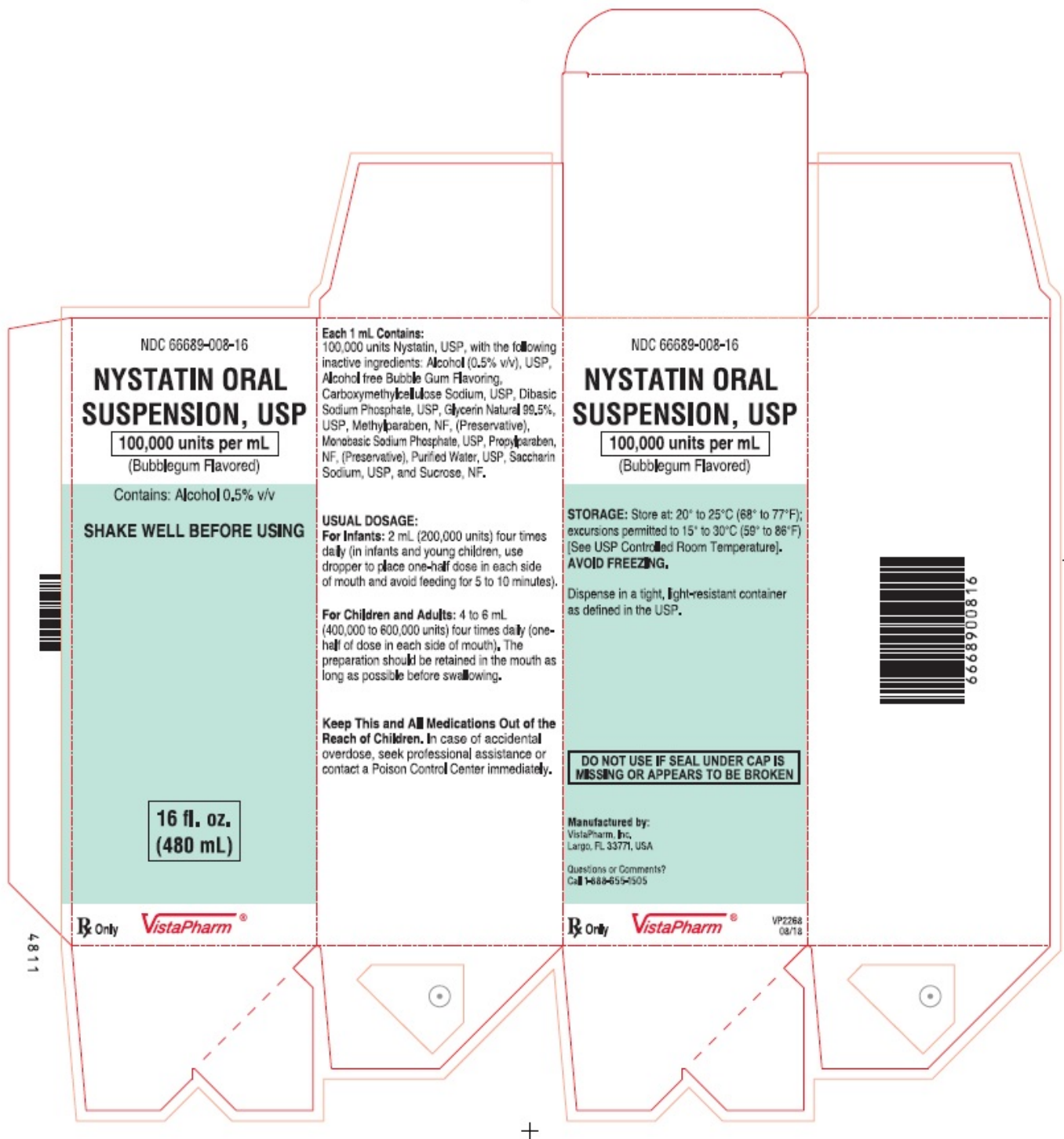
SHAKE WELL BEFORE USING

16 fl. oz.

(480 mL)

Rx only

VistaPharm®



NYSTATIN

nystatin suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66689-008
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)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
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)