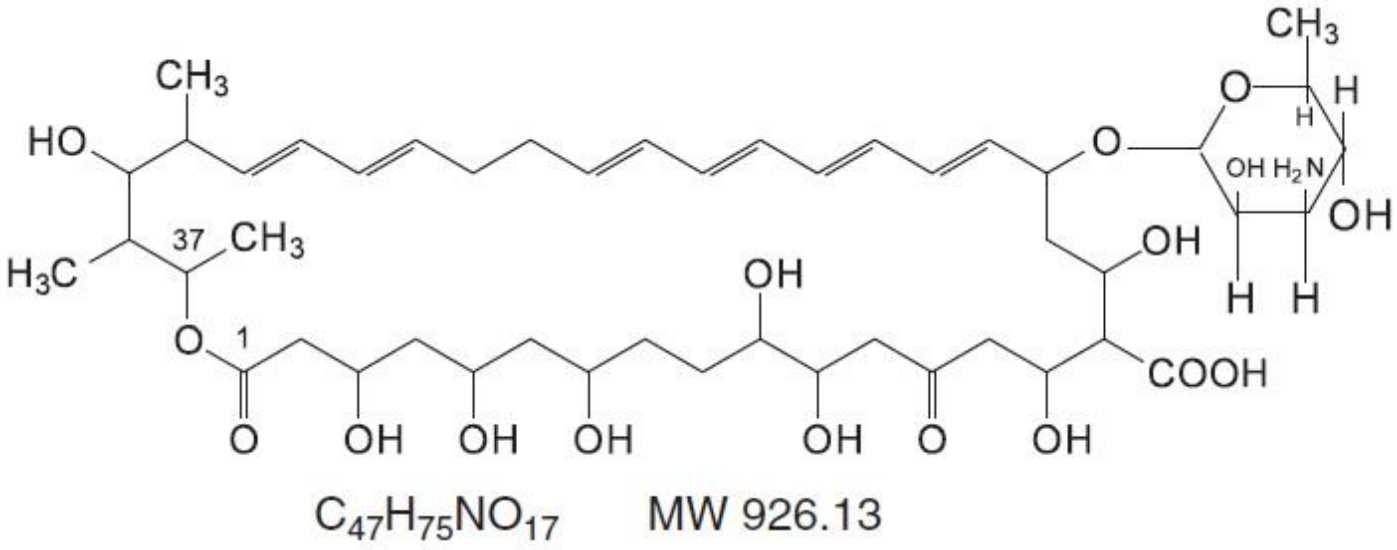
NYSTATIN- nystatin suspension
VistaPharm, LLC

NYSTATIN ORAL SUSPENSION, USP 100,000 Units/mL

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 Nystatin Units per mL.

Inactive ingredients (cherry flavor): alcohol (1% v/v), methylparaben, NF; dibasic sodium phosphate, USP; monobasic sodium phosphate, USP; saccharin sodium, USP; sucrose (50% w/v), NF; glycerin, USP; carboxy-methylcellulose sodium, USP; propylparaben, NF; artificial wild cherry flavor # 14783 and purified water, USP.

Inactive ingredients (bubblegum flavor): Alcohol (0.5% v/v), USP, Alcohol free Bubblegum 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 REACTIONS, contact VistaPharm, Inc., at 1-888-655-1505 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 Nystatin Units per mL, cherry flavored, light creamy yellow, ready-to-use
suspension, is available as follows:

NDC 66689-037-01: 5 mL unit dose cup.

NDC 66689-037-50: Case contains 50 unit dose cups of 5 mL (NDC 66689-037-01), packaged in 5 trays of 10 unit dose cups each.

NDC 66689-037-99: Case contains 100 unit dose cups of 5 mL (NDC 66689-037-01), packaged in 10 trays of 10 unit dose cups each.

Nystatin Oral Suspension, USP, 100,000 Nystatin units per mL, bubblegum flavored, yellow opaque, ready-to-use suspension 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° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

AVOID FREEZING.

Rx Only

Manufactured by:

Largo, FL 33771

VP2053R2
06/22

PRINCIPAL DISPLAY PANEL - Unit Dose Cup

Nystatin

Oral Suspension, USP

500,000 units/5 mL

Alcohol not more than 1% v/v

SHAKE WELL. AVOID FREEZING.

Delivers 5 mL

Store at 20°–25°C (68°–77°F); see USP CRT conditions.

Manufactured by:

Largo, FL 33771, USA

Xact DOSE™

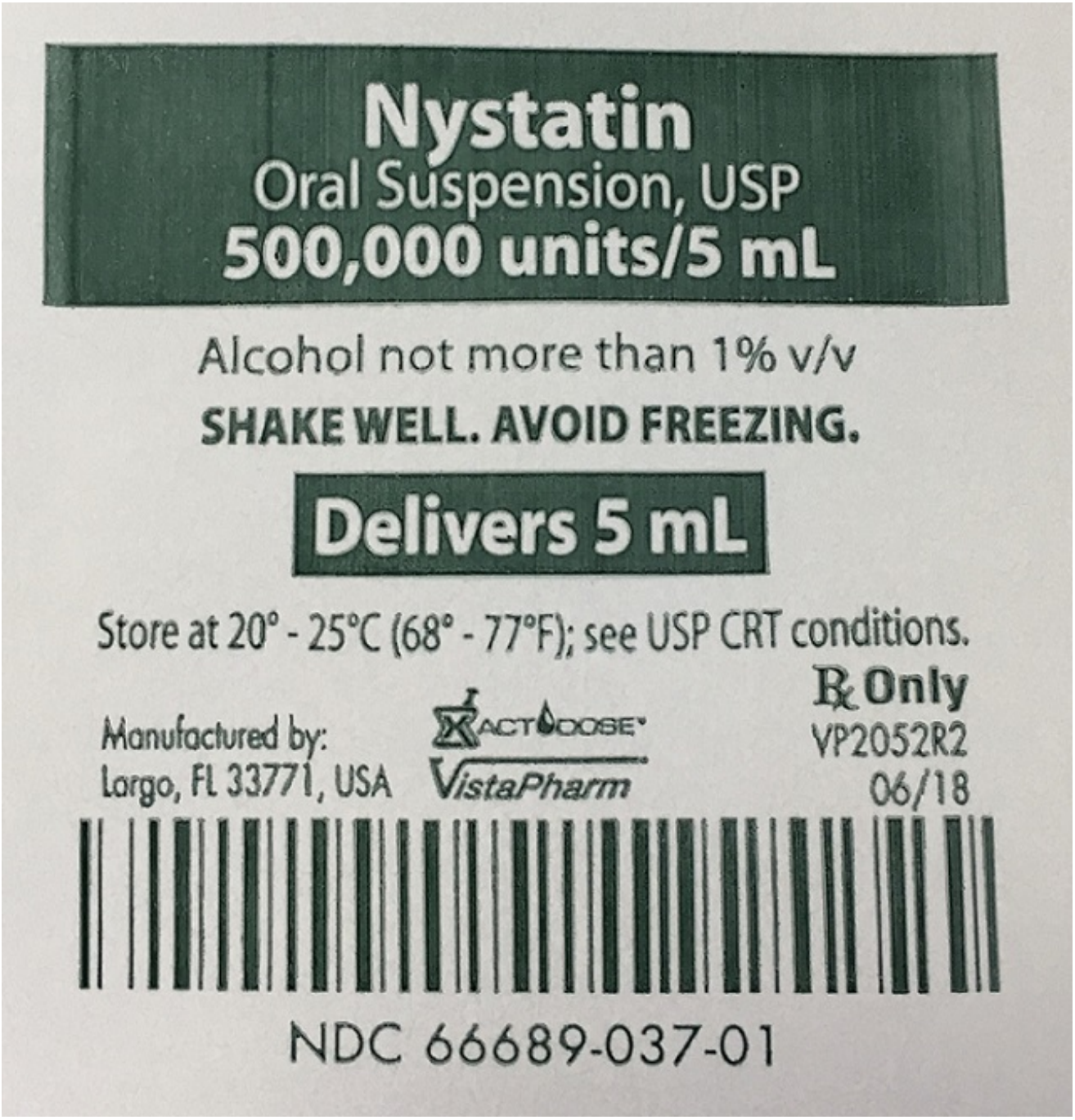
VistaPharm

Rx Only

VP2052R2

06/18

NDC 66689-037-01



PRINCIPAL DISPLAY PANEL - 60 mL

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

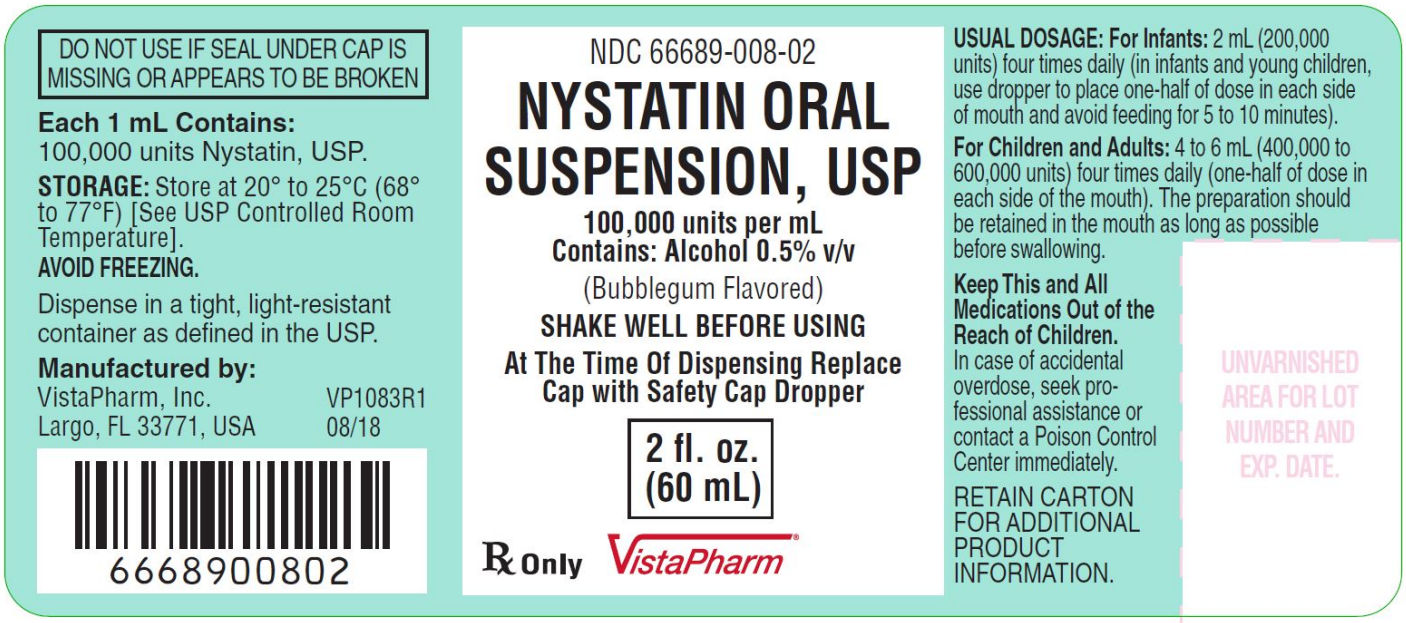
Cap with Safety Cap Dropper

2 fl. oz.

(60 mL)

Rx only

VistaPharm®



NDC 66689-008-02

NYSTATIN ORAL

SUSPENSION, USP

100,000 units per mL

Contains: Alcohol 0.5% v/v

(Bubblegum Flavored)

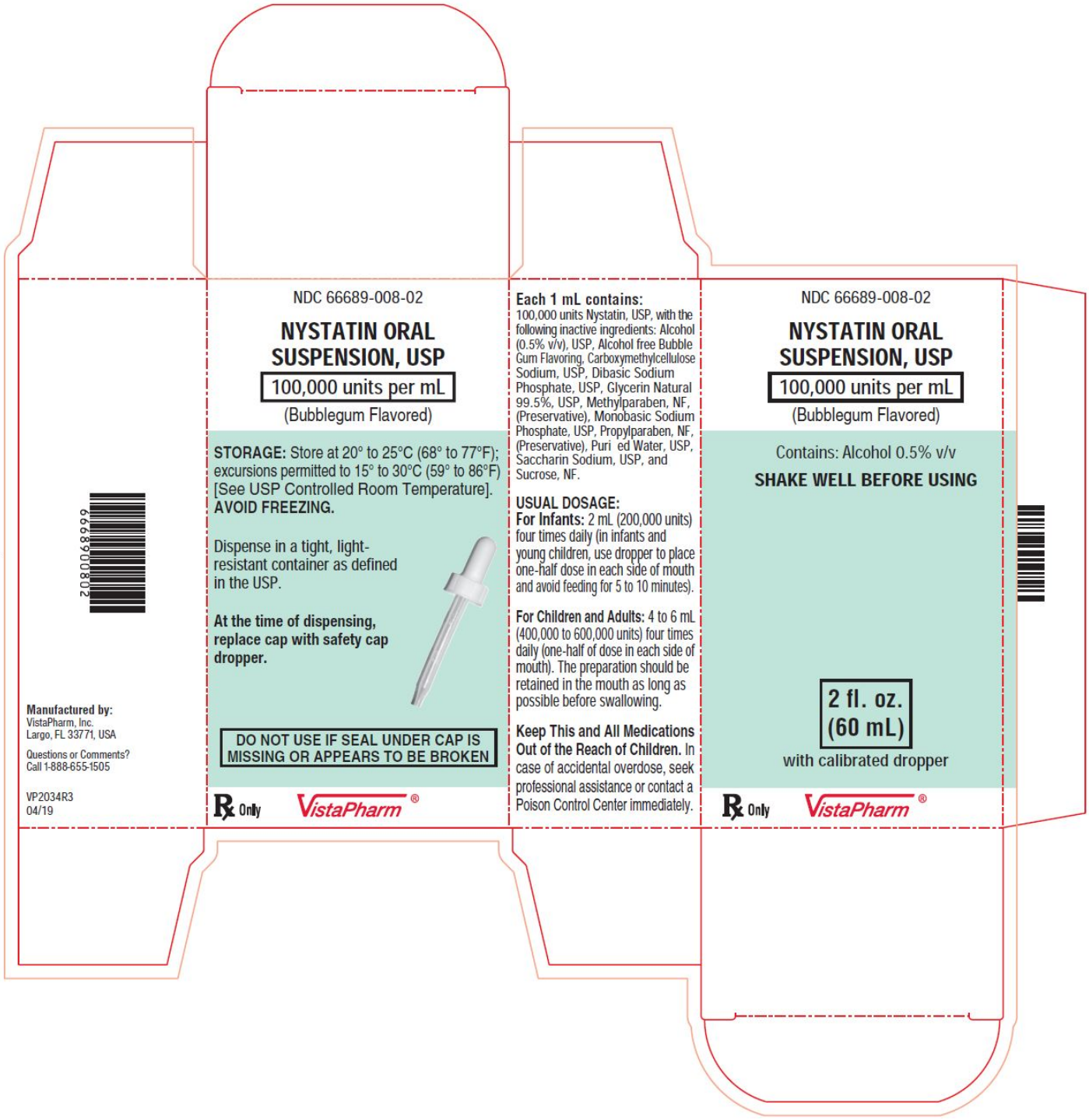
SHAKE WELL BEFORE USING

2 fl. oz.

(60 mL)

Rx only

VistaPharm®



PRINCIPAL DISPLAY PANEL - 480 mL

NDC 66689-008-16

NYSTATIN ORAL

SUSPENSION, USP

100,000 units per mL

Contains: Alcohol 0.5% v/v

(Bubblegum Flavored)

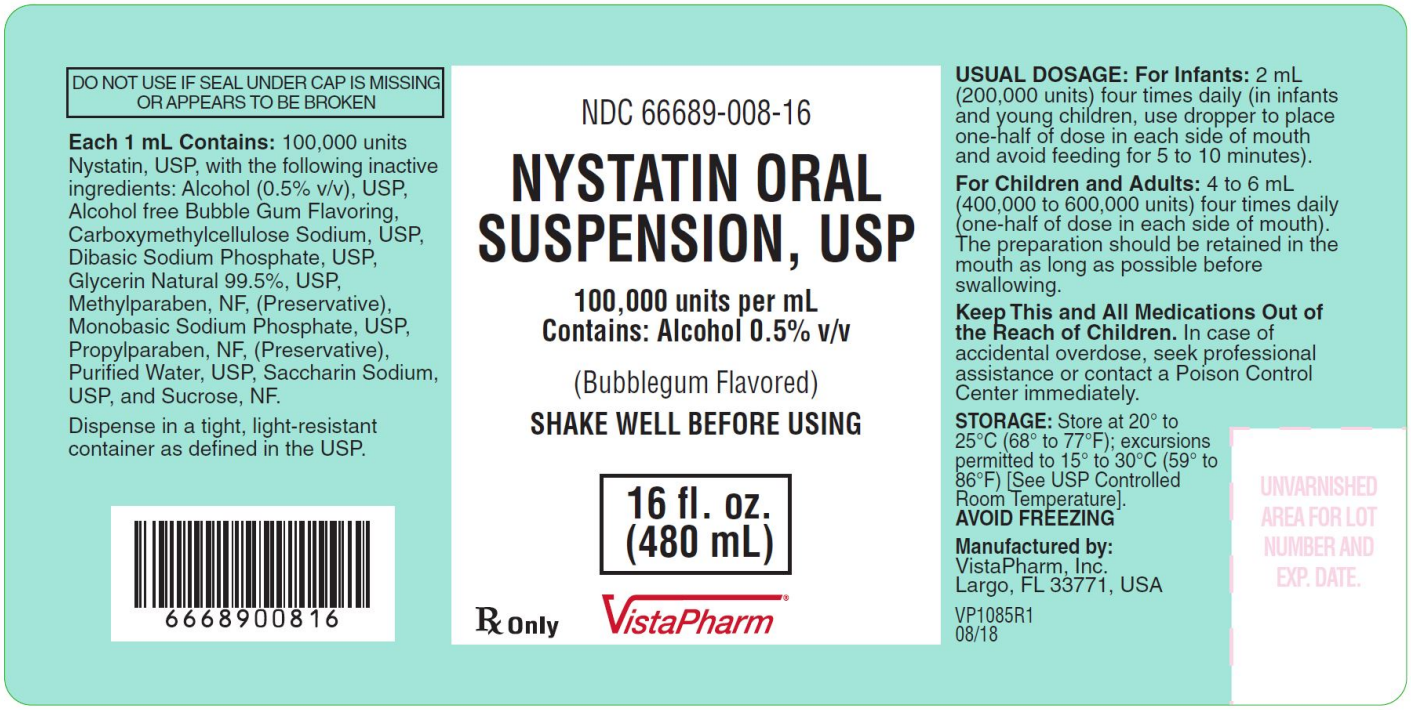
SHAKE WELL BEFORE USING

16 fl. oz.

(480 mL)

Rx only

VistaPharm®



NDC 66689-008-16

NYSTATIN ORAL

SUSPENSION, USP

100,000 units per mL

(Bubblegum Flavored)

Contains: Alcohol 0.5% v/v

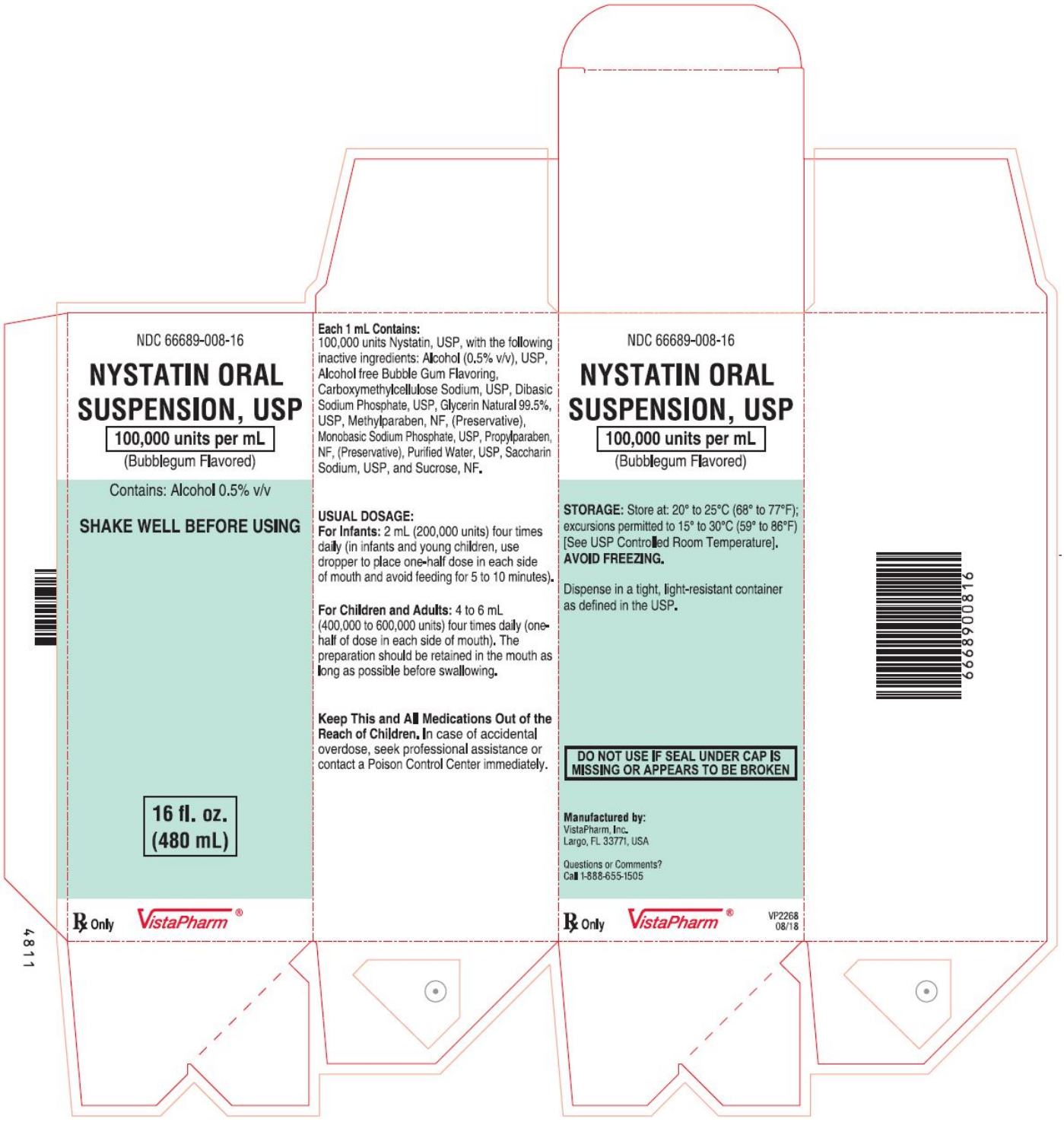
SHAKE WELL BEFORE USING

16 fl. oz.

(480 mL)

Rx only

VistaPharm®



NYSTATIN

nystatin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66689-037
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
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	yellow (Light yellow)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66689-037-50	5 in 1 CASE	05/10/2010	02/28/2025
1		10 in 1 TRAY		
1	NDC:66689-037-01	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:66689-037-99	10 in 1 CASE	05/10/2010	02/28/2025
2		10 in 1 TRAY		
2	NDC:66689-037-01	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	ANDA064142	05/10/2010	02/28/2025

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	02/28/2025
2	NDC:66689-008-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	02/28/2025
3	NDC:66689-008-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	02/28/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064142	05/01/2012	02/28/2025

Labeler - VistaPharm, LLC (048458728)

Revised: 7/2024 VistaPharm, LLC