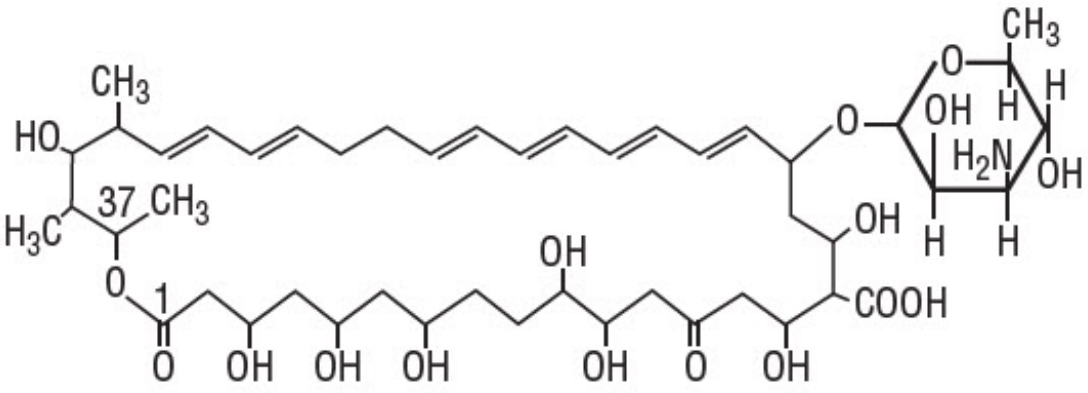
NYSTATIN- nystatin suspension
Nivagen Pharmaceuticals, Inc.

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, is cherry/mint flavored, containing 100,000 USP Nystatin Units per mL. Inactive ingredients: disodium edetate, sodium benzoate, sodium hexametaphosphate, dibasic sodium phosphate heptahydrate, monobasic sodium phosphate monohydrate, glycerin, methyl paraben, propyl paraben, sucrose, cherry flavor and peppermint oil.

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 cherry-mint flavored, yellow, ready-to-use suspension.

60 mL bottles with a 1 mL calibrated dropper (NDC: 75834-235-60) and 1 Pint (473 mL) bottles (NDC: 75834-235-16)

SHAKE WELL BEFORE USE

Storage

Store at 20° - 25°C (68° - 77°F); excursions permitted between 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. AVOID FREEZING.

PHARMACIST: Dispense in a tight light-resistant container as defined in USP.

Manufactured for:
Nivagen Pharmaceuticals, Inc.
Sacramento, CA 95827
Toll Free Number: 1-877-977-0687

Rev: 06/2020

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Carton

NDC 75834-235-60

NYSTATIN ORAL
SUSPENSION, USP
(100,000 units per mL)

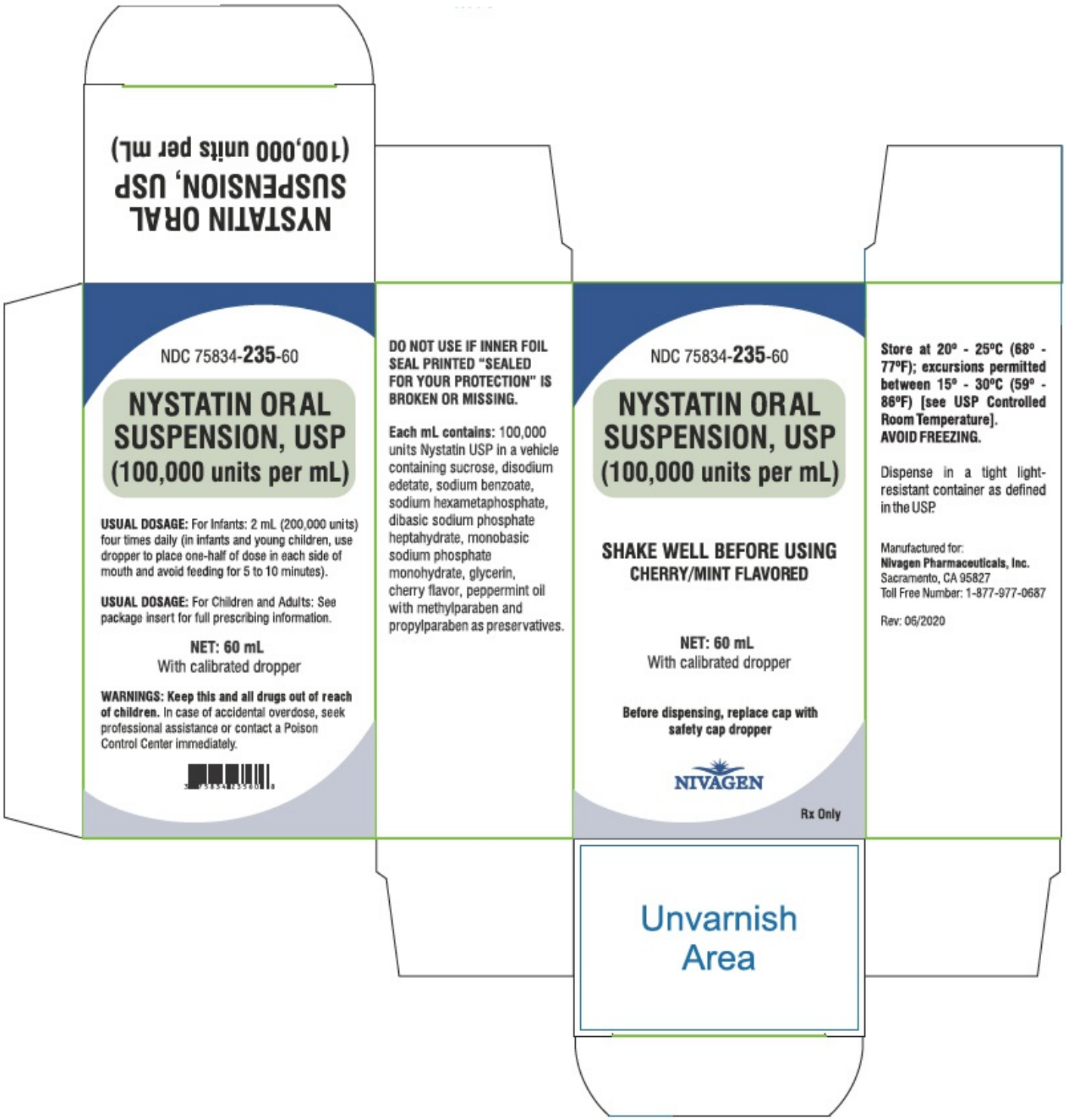
SHAKE WELL BEFORE USING
CHERRY/MINT FLAVORED

NET: 60 mL
With calibrated dropper

Before dispensing, replace cap with
safety cap dropper

NIVAGEN

Rx Only



NYSTATIN

nystatin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75834-235
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
HEXASODIUM HEXAMETAPHOSPHATE (UNII: N40N91DW96)	
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SUCROSE (UNII: C151H8M554)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Product Characteristics

Color	YELLOW	**Score**	
Shape		**Size**	
Flavor	CHERRY (MINT)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75834-235-60	1 in 1 CARTON	08/14/2020	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:75834-235-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062832	08/14/2020	

Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Revised: 2/2022 Nivagen Pharmaceuticals, Inc.