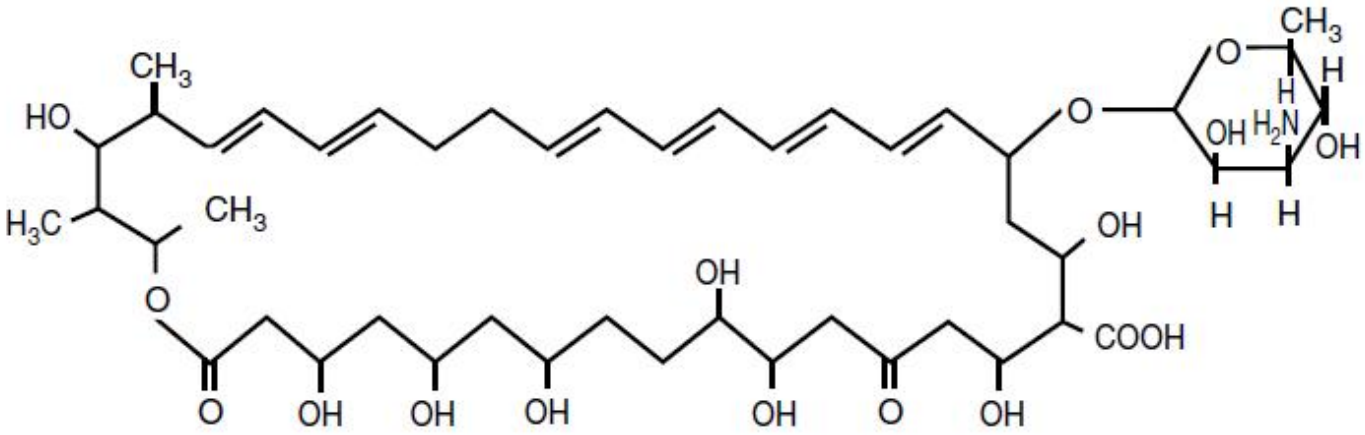
NYSTATIN- nystatin suspension
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

Nystatin Oral Suspension, USP

Rx Only

DESCRIPTION

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



Molecular Formula: $C_{47}H_{75}NO_{17}$ Molecular Weight: 926.13

Nystatin Oral Suspension, for oral administration, contains 100,000 USP Nystatin Units per mL. Inactive ingredients: alcohol USP (not more than 1% by volume), mint blend flavoring, dibasic sodium phosphate USP, glycerin USP, purified water USP, colloidal silicon dioxide, sucrose NF (50%), methylparaben NF (0.12%) and propylparaben NF (0.03%) as preservatives.

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–*Pregnancy 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.

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 (approximately 1/2 teaspoon)(200,000 units) four times daily 1 mL (approximately 1/4/ teaspoon) (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 (approximately 1 teaspoon)(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 mint-flavored, light yellow, ready-to-use suspension in the following sizes:

NDC 0168-0037-60 60 mL bottle (with a calibrated dosing cup)
NDC 0168-0037-61 60 mL bottle (with a calibrated dropper)
NDC 0168-0037-74 1 Pint bottle

Shake well before using. Wash cup before and after each use.
Before dispensing, replace cap with safety cap dropper.

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

WARNING: Keep out of reach of children.

This product sealed for your protection. If the seal is missing or broken return to place of purchase.

E. FOUGERA & CO.
A division of Nycomed US Inc.
Melville, New York 11747

I237C/IF237E
R11/07
#276

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60ML CONTAINER

NDC 0168-0037-60

FOUGERA®

NYSTATIN ORAL

SUSPENSION USP

100,000 USP Nystatin Units per mL

Rx only

60mL

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60ML CARTON

NDC 0168-0037-60

FOUGERA®

NYSTATIN ORAL

SUSPENSION USP

100,000 USP

Nystatin Units per mL

Rx only

60mL

with Dose

Measuring Cup

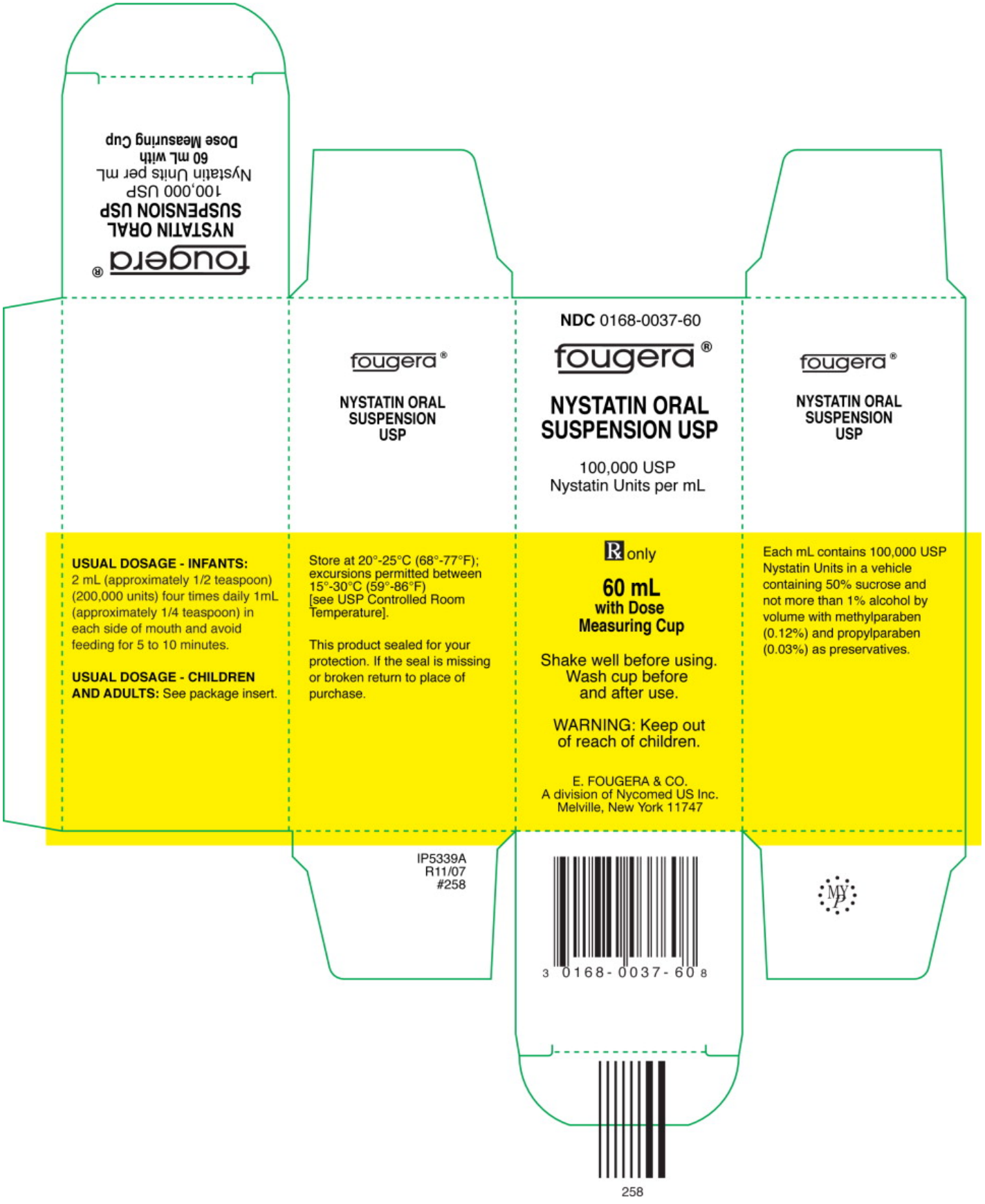
Shake well before using.

Wash cup before

and after use.

WARNING: Keep out

of reach of children.



NYSTATIN
nystatin suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0037
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)	
sodium phosphate, dibasic (UNII: GR686LBA74)	
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sucrose (UNII: C151H8M554)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0037-60	1 in 1 CARTON		
1		60 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062517	06/07/1984	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Establishment

Name	Address	ID/FEI	Business Operations
Fougera Pharmaceuticals Inc.		043838424	ANALYSIS(0168-0037)

Establishment

Name	Address	ID/FEI	Business Operations
Fougera Pharmaceuticals Inc.		174491316	MANUFACTURE(0168-0037)

Revised: 7/2012

E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.