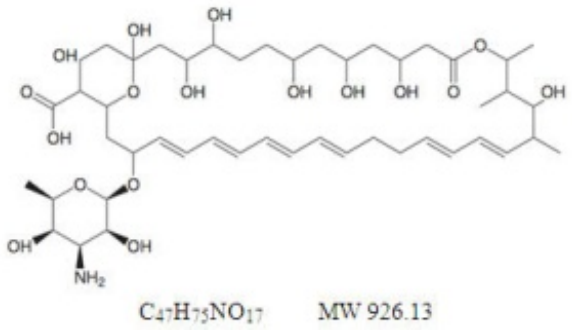
NYSTATIN- nystatin tablet, film coated
Sun Pharmaceutical Industries, Inc.

NYSTATIN TABLETS USP (oral)

Rx only

DESCRIPTION

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



Nystatin tablets are provided for oral administration as coated tablets containing 500,000 units nystatin.

Inactive ingredients: anhydrous lactose, carnauba wax, corn starch, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, and titanium dioxide.

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 tablets are intended for the treatment of non-esophageal mucus membrane gastrointestinal candidiasis.

CONTRAINDICATIONS

Nystatin tablets are contraindicated in patients with a history of hypersensitivity to any of their 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. It is also not known whether nystatin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin 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.

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 of superinfections (see **CLINICAL PHARMACOLOGY, Pharmacokinetics**).

DOSAGE AND ADMINISTRATION

The usual therapeutic dosage is one to two tablets (500,000 to 1,000,000 units nystatin) three times

daily. Treatment should generally be continued for at least 48 hours after clinical cure to prevent relapse.

HOW SUPPLIED

Nystatin tablets, USP 500,000 units, are round, brown, film coated, debossed MP 83. Available as follows:

Bottles of 50	NDC 53489-400-02
Bottles of 100	NDC 53489-400-01
Bottles of 250	NDC 53489-400-03
Bottles of 500	NDC 53489-400-05
Bottles of 1000	NDC 53489-400-10

Store at 20° to 25°C (68° to 77°F).

[See USP Controlled Room Temperature]

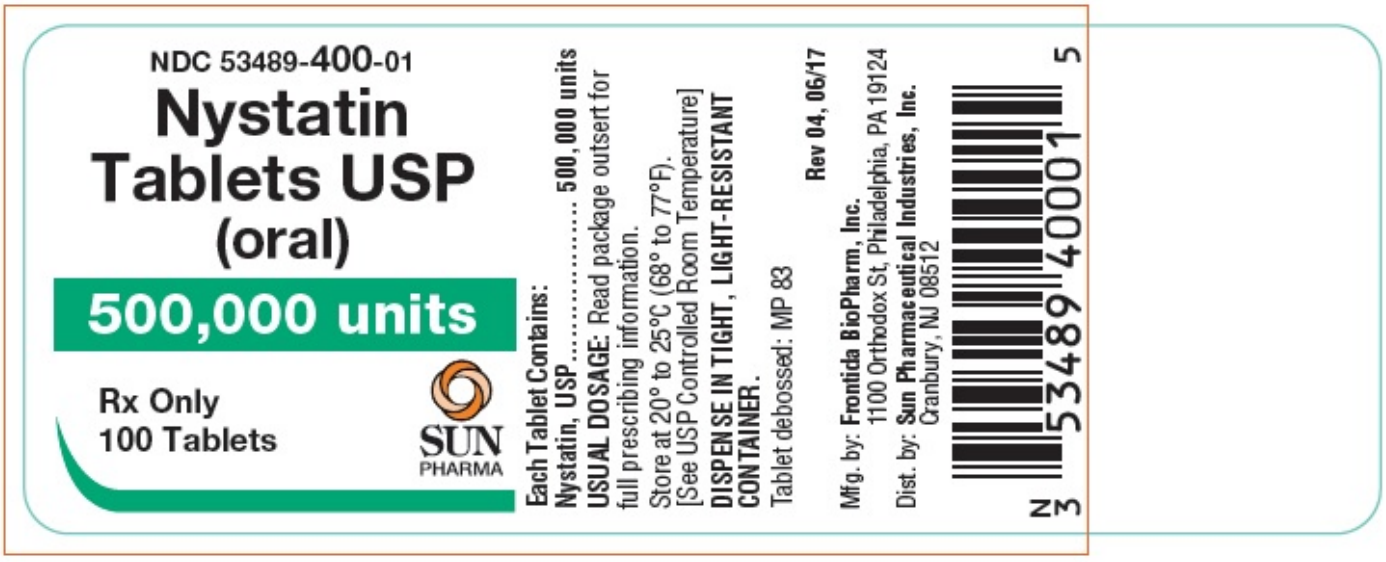
DISPENSE IN TIGHT, LIGHT-RESISTANT CONTAINER.

Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

Rev 02, November 2014

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NystatinTablets USP (oral)- 100 tablets



NYSTATIN
nystatin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53489-400

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
nystatin (UNII: BDF1O1C72E) (nystatin - UNII:BDF1O1C72E)	nystatin	500000 [USP'U]

Inactive Ingredients

Ingredient Name	Strength
anhydrous lactose (UNII: 3SY5LH9PMK)	
carnauba wax (UNII: R12CBM0EIZ)	
starch, corn (UNII: O8232NY3SJ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYDROXYPROPYL CELLULOSE (120000 MW) (UNII: UKE75GEA7F)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
starch, potato (UNII: 8I089SAH3T)	
stearic acid (UNII: 4ELV7Z65AP)	
titanium dioxide (UNII: 15FIX9V2JP)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	MP;83
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53489-400-02	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/1988	
2	NDC:53489-400-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/1988	
3	NDC:53489-400-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/1988	
4	NDC:53489-400-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/1988	
5	NDC:53489-400-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/1988	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062838	12/22/1988	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Frontida BioPharm Inc.		080243260	MANUFACTURE(53489-400) , ANALYSIS(53489-400) , PACK(53489-400)

Revised: 1/2018 Sun Pharmaceutical Industries, Inc.