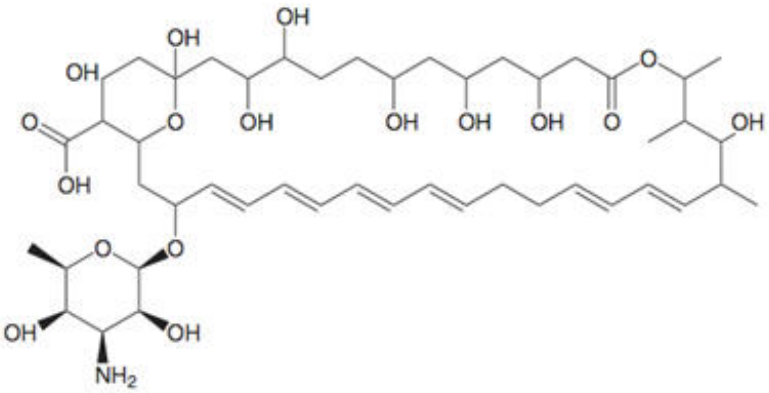
NYSTATIN- nystatin tablet, film coated
Aidarex Pharmaceuticals LLC

NYSTATIN TABLETS USP (oral)

Rx only

DESCRIPTION

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



$C_{47}H_{75}NO_{17}$ MW 926.13

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

Inactive ingredients: anhydrous lactose, carnauba wax, corn starch, 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 30	NDC 33261-0896-30

Store at 20° to 25°C (68° to 77°F).

[See USP Controlled Room Temperature]

DISPENSE IN TIGHT, LIGHT-RESISTANT CONTAINER.

Manufactured by:
MUTUAL PHARMACEUTICAL COMPANY, INC.
Philadelphia, PA 19124 USA

Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880

Rev 01, July 2009

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle

NDC 33261-0896-30

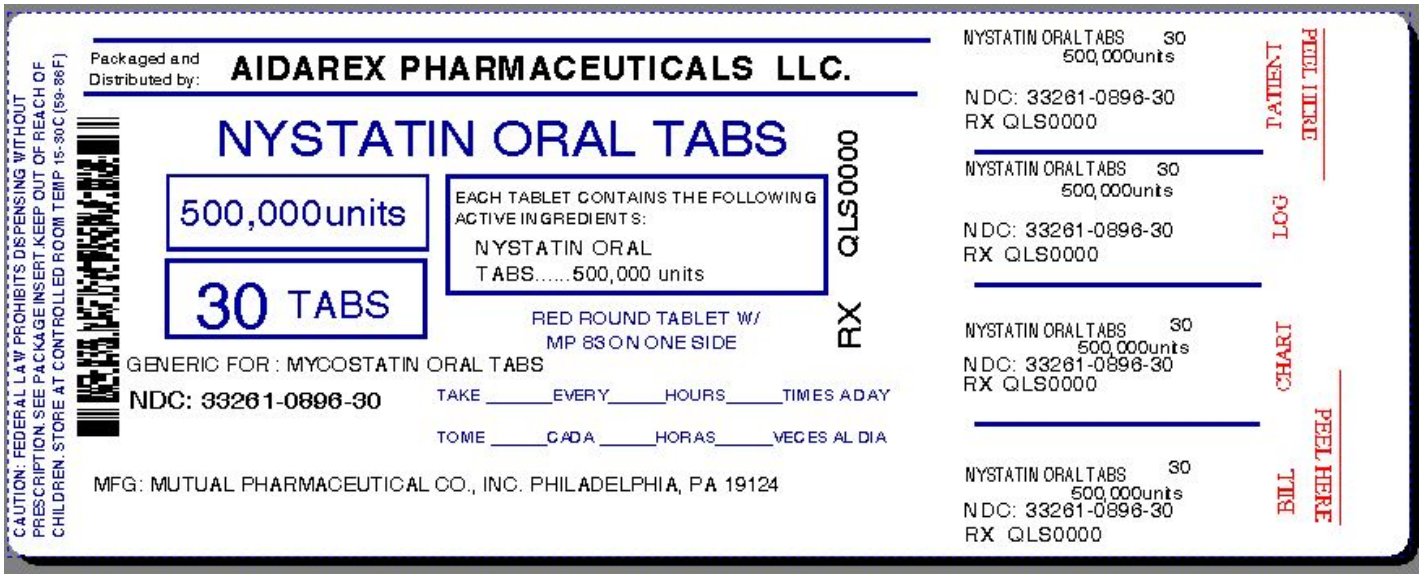
NYSTATIN TABLETS USP
(ORAL)

500,000 units

30 TABLETS
Rx only

MUTUAL PHARMACEUTICAL CO., INC.
PHILADELPHIA, PA 19124 USA

Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880



NYSTATIN

nystatin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:33261-896(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 (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, POTATO (UNII: 8I089SAH3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:33261-896-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

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

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 1/2014 Aidarex Pharmaceuticals LLC