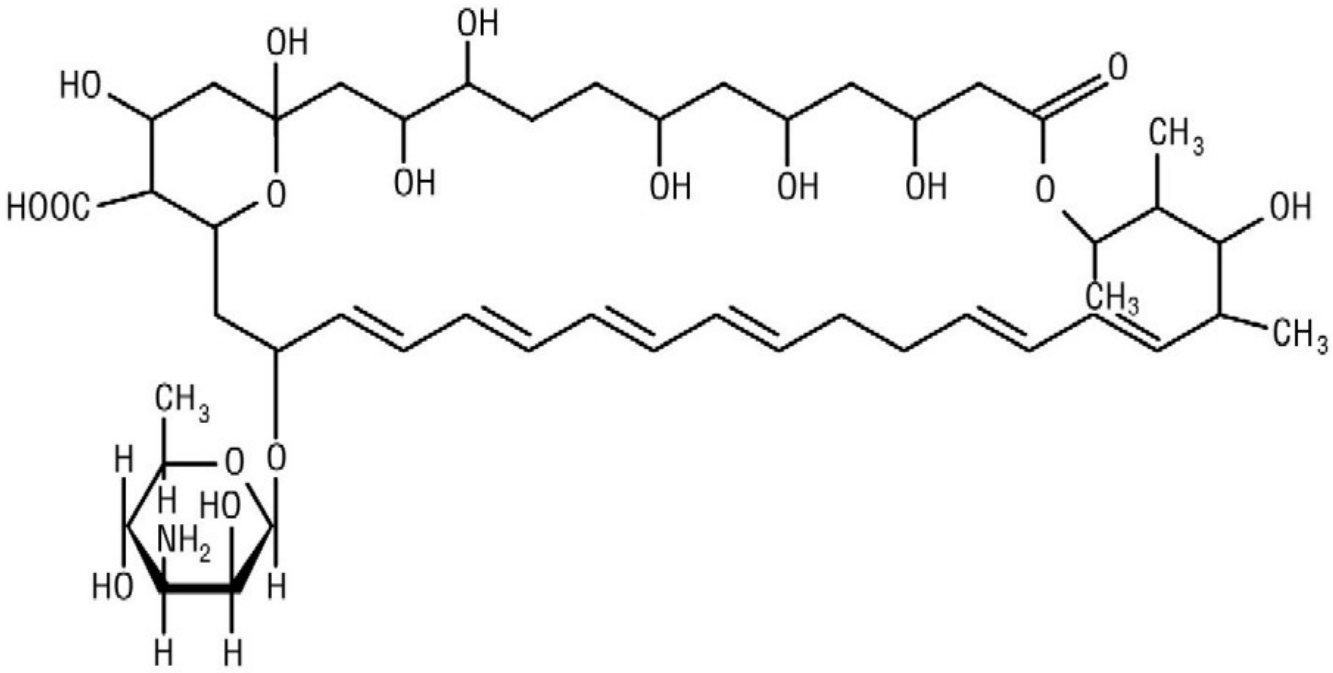
NYSTATIN- nystatin tablet, film coated
Teva Pharmaceuticals USA, Inc.

Nystatin Tablets USP
Rx only
0983

DESCRIPTION

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



$C_{47}H_{75}NO_{17}$ M.W. 926.13

Nystatin Tablets USP contain the inactive ingredients: Corn Starch, Povidone, Compressible Sugar, Microcrystalline Cellulose, Sodium Starch Glycolate, Talc, Magnesium Stearate, Purified Water, and Coloring.

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

Pregnancy 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, convex, brown, film-coated tablet debossed with 93 on one side and 983 on the reverse and are packaged in bottles of 100 tablets (NDC 0093-0983-01).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Keep tightly closed.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured By:

TEVA CANADA LIMITED

Toronto, Canada M1B 2K9

Manufactured For:

TEVA PHARMACEUTICALS USA, INC.

North Wales, PA 19454

Rev. N 2/2016

Package/Label Display Panel

NDC 0093-0983-01

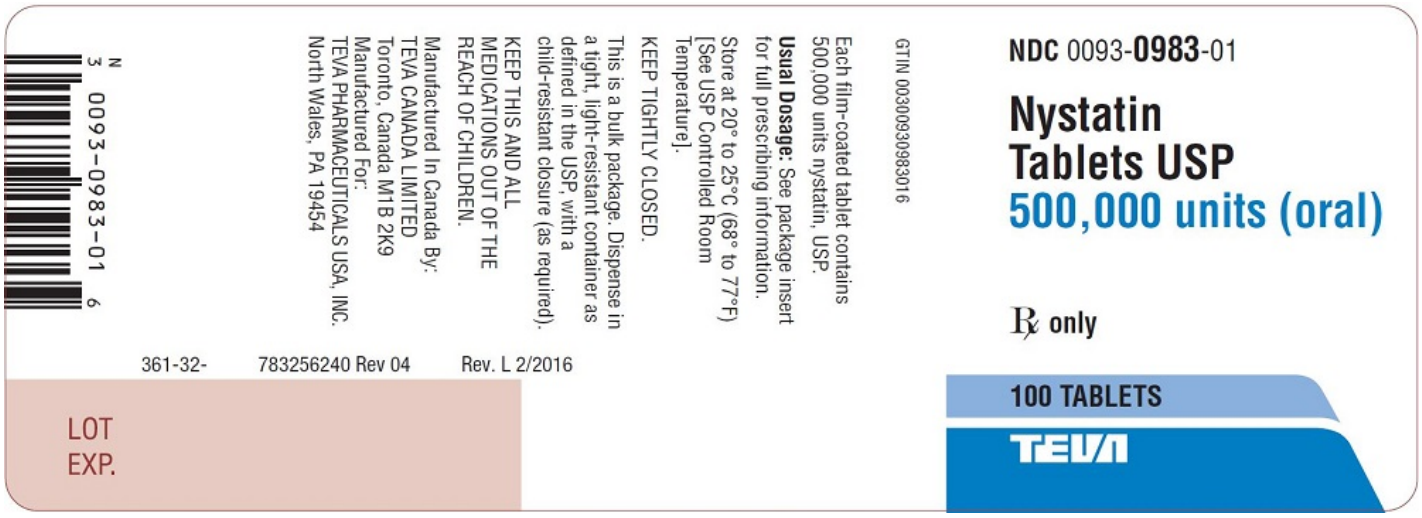
Nystatin

Tablets USP

500,000 units (oral)

Rx only

100 TABLETS



NYSTATIN

nystatin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0093-0983
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
SUCROSE (UNII: C151H8M554)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	93;983
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0093-0983-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062506	09/30/1990	

Labeler - Teva Pharmaceuticals USA, Inc. (001627975)

Revised: 2/2016 Teva Pharmaceuticals USA, Inc.