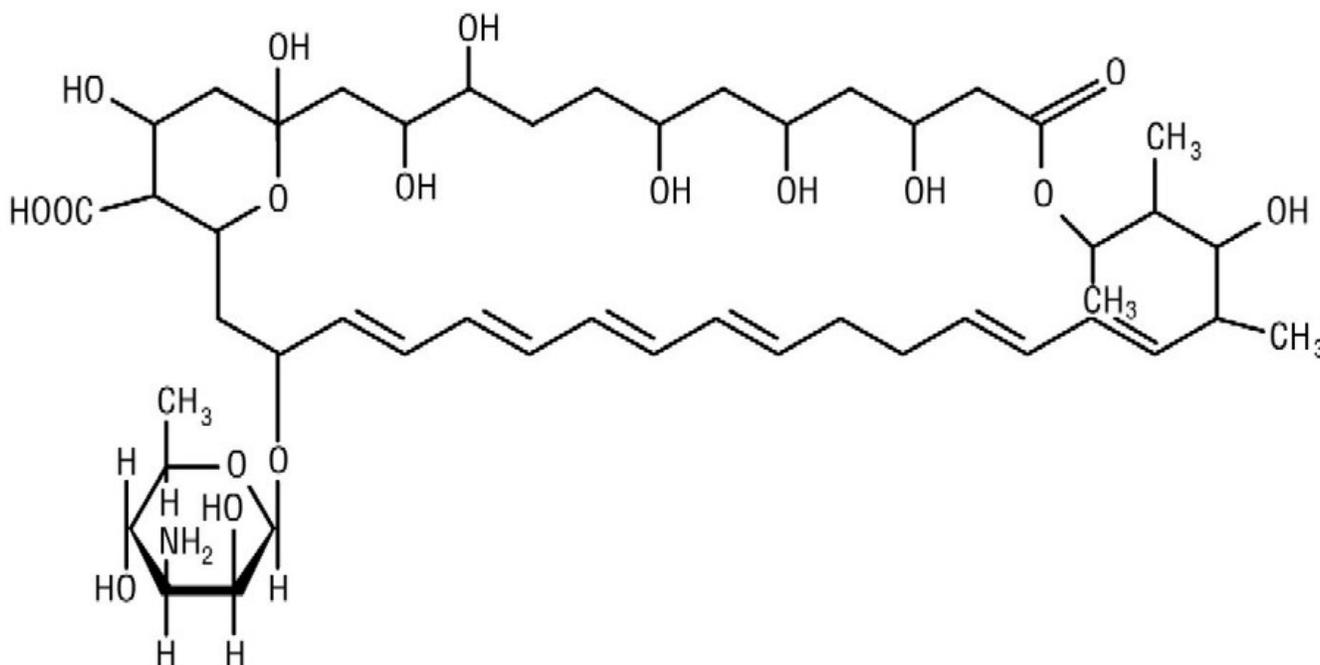


NYSTATIN- nystatin tablet, film coated
Carilion Materials Management

NYSTATIN TABLETS USP 0983 Rx only

DESCRIPTION

Nystatin is an antimycotic polyene antibiotic obtained from *Streptomyces noursei*



C₄₇H₇₃N₁O₂₁ M.W. 926.13 477517

Nystatin tablets 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 against a wide variety of yeasts and yeast like fungi.

demonstrates no significant resistance to nystatin on repeated subculture in increasing levels of nystatin; other species become quite resistant. Generally, resistance does not develop. Nystatin acts by binding to sterols in the cell membrane of susceptible species with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses. *in vitro* *Candida albicans* *in vitro* *Candida* *in vivo* *Candida*

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

NDC:68151-1487-0 in a PACKAGE of 1 TABLET, FILM COATEDS

Nystatin 500,000 units



Nystatin Tablets USP 500,000 units (Oral) 100 Label Text

0093- -01 NDC0983

NYSTATIN

Tablets USP

500,000 units (oral)

Rx only

100 TABLETS

TEVA

NYSTATIN			
nystatin tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68151-1487(NDC:0093-0983)

Route of Administration	ORAL
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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 K29/32 (UNII: 390RMW2PEQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

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:68151-1487-0	1 in 1 PACKAGE		

Marketing Information

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

Labeler - Carilion Materials Management (079239644)

Registrant - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-1487)