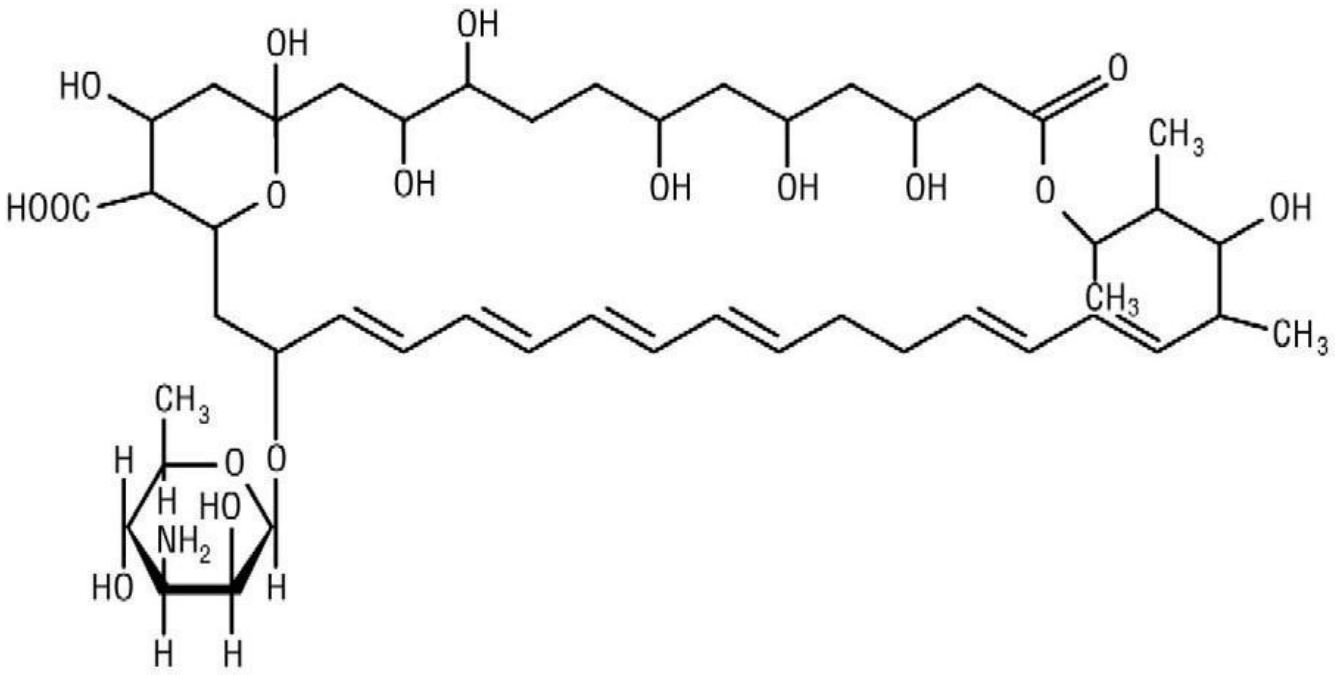
NYSTATIN- nystatin tablet, coated
Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.

Nystatin Tablets, USP (Oral)
Rx only

DESCRIPTION

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



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

Nystatin tablets are for oral administration and contain 500,000 units of nystatin per tablet.

Nystatin tablets contain the inactive ingredients: corn starch, confectioner sugar, dibasic calcium phosphate, FD&C yellow #6, FD&C red #40, FD&C blue # 2, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, magnesium stearate, polyethylene glycol, polysorbate 80, talc 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.

To report SUSPECTED ADVERSE REACTIONS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 tablets debossed "HP51" on one side and plain on the other side are packaged in:

Bottles of 100: NDC 23155-051-01

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

Manufactured by:

Strides Pharma Science Limited

Puducherry- 605 014, India.

PON/DRUGS/16 13 4193

Distributed by:

Avet Pharmaceuticals Inc.

East Brunswick, NJ 08816

1.866.901.DRUG (3784)

1041073

Rev: 06/2020

OR

Manufactured by:

Vivimed Life Sciences Private Limited

Alathur, Kanchipuram – 603 110, Tamilnadu, India.

M.L. No.: TN00002327

Manufactured for:

Avet Pharmaceuticals Inc.

East Brunswick, NJ 08816

1.866.901.DRUG(3784)

1043190

Revised: 08/2021

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Nystatin Tablets USP, 500,000 Units, 100 count bottles

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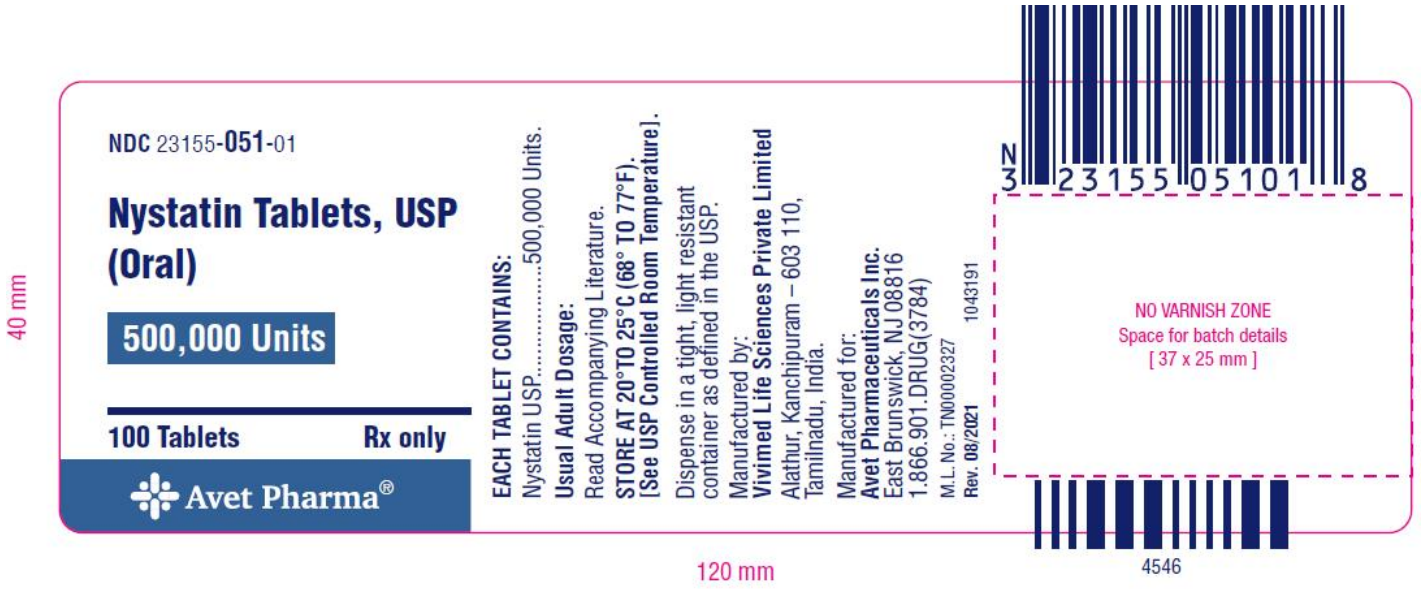

label
label

NYSTATIN

nystatin tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23155-051
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)	
SUCROSE (UNII: C151H8M554)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	HP;51
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-051-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062474	10/31/2011	

Labeler - Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc. (780779901)

Registrant - Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc. (780779901)

Establishment

Name	Address	ID/FEI	Business Operations

Strides Pharma Science Limited		871402375	MANUFACTURE(23155-051) , ANALYSIS(23155-051) , PACK(23155-051)

Establishment

Name	Address	ID/FEI	Business Operations
Vivimed Life Sciences Private Limited		860477684	ANALYSIS(23155-051) , MANUFACTURE(23155-051) , PACK(23155-051)

Establishment

Name	Address	ID/FEI	Business Operations
Capua Bioservices S.p.A.		447961004	ANALYSIS(23155-051) , API MANUFACTURE(23155-051)