
Nystatin

Nvstatin

Tablet.

Nystatin

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

NDC: 63629-8350-3: 30 Tablets in a BOTTLE

NDC: 63629-8350-1: 28 Tablets in a BOTTLE

NDC: 63629-8350-2: 56 Tablets in a BOTTLE

Nystatin(oral) 500,000 Units Tablet

Packaged by Bryant Ranch Prepack

Burbank, CA 91504

Nystatin(oral) 500,000 Units Tablet

LOT 1523487

BROWN ROUND HP;51

Compare To

Nystatin(oral) 500,000
Units Tablet

Strides Pharma Science Limited

RX Only

Store at room temp of
20°-25°C (68°-77°F)

Keep all drugs out of
reach of children.

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EXP MM/YY

NDC

6362983501



08350281523487

NYSTATIN

nystatin tablet, coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63629-8350(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)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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:63629-8350-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/05/2020	
2	NDC:63629-8350-1	28 in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2022	
3	NDC:63629-8350-2	56 in 1 BOTTLE; Type 0: Not a Combination Product	09/02/2020	

Marketing Information

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

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-8350) , RELABEL(63629-8350)