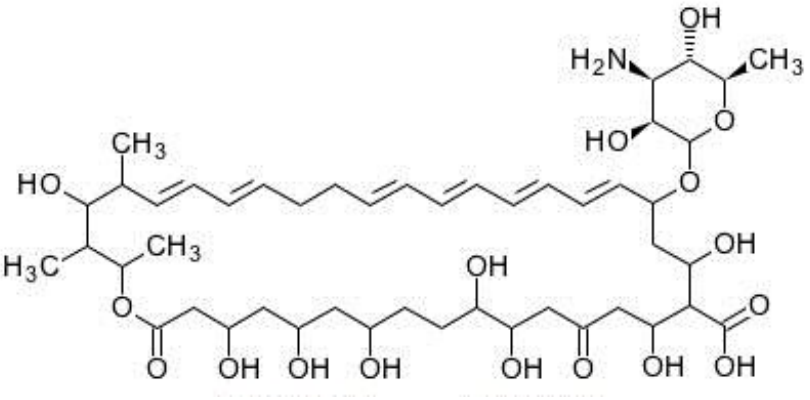
NYSTATIN- nystatin suspension
Hi-Tech Pharmacal Co., Inc.

Nystatin Oral Suspension, USP
100,000 units per mL

DESCRIPTION

Nystatin is obtained from *Streptomyces noursei*. It is known to be a mixture, but the composition has not been completely elucidated. Nystatin A is closely related to amphotericin B. Each is a macro-cyclic lactone containing a ketal ring, an *all-trans* polyene system, and a mycosamine (3-amino-3-deoxyrhamose) moiety.

Its structural formula is:



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

Nystatin oral suspension, USP is a cherry-mint flavored, ready-to-use suspension. Each mL of nystatin oral suspension, USP contains 100,000 units of nystatin in a vehicle containing 50% w/v sucrose with the following inactive ingredients: alcohol (less than 1% v/v), carboxymethylcellulose sodium, cherry flavor, citric acid, glycerin, peppermint flavor, purified water, and sodium citrate. Citric acid and/or sodium hydroxide may be used to adjust pH (5.3-7.5).

PRESERVATIVES ADDED: Methylparaben 0.12%, Propylparaben 0.03%

CLINICAL PHARMACOLOGY

Nystatin acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin is absorbed very sparingly following oral administration, with no detectable blood levels when given in the recommended doses.

INDICATIONS AND USAGE

Nystatin oral suspension, USP is indicated for the treatment of infections of the oral cavity caused by *Candida albicans*.

CONTRAINDICATIONS

Nystatin is contraindicated in patients with a history of hypersensitivity to nystatin or any of the

suspension components.

PRECAUTIONS

General

Discontinue treatment with nystatin if sensitization or irritation is reported during use.

Nystatin is not effective in the treatment of systemic mycoses since it is not significantly absorbed from the gastrointestinal tract.

Information for Patients

Patient should be advised to retain nystatin in the mouth as long as possible and to continue its use for at least 2 days after symptoms have subsided.

There should be no interruption or discontinuation of the medication until the prescribed course of treatment is completed, even though symptomatic relief may occur within a few days.

If symptoms of local irritation develop, the physician should be notified immediately.

Laboratory Tests

If there is a lack of therapeutic response, appropriate microbiological studies (e .g., KOH smears and/or cultures) should be repeated to confirm the diagnosis of candidiasis and rule out other pathogens before instituting another course of therapy.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. In mice exposed to nystatin 50 mg/kg by injection, an increased incidence of chromosomal aberrations, consisting primarily of chromatid breaks, was observed in bone marrow cells. However, there have been no studies to determine the mutagenicity of orally-administered nystatin or its effects on fertility in males or females.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Teratogenicity 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.

Nonteratogenic Effects

In one rat reproductive study, nystatin was administered orally to pregnant rats in single doses of 100, 500, or 3000 mg/kg on the ninth day of gestation, or as multiple doses of 500 mg/kg/day on gestation days 1-20, 1-4, 7-10, 11-14, or 15-18. It was found that nystatin had a slight abortive effect when used during the whole period of pregnancy. No abnormalities were seen in surviving fetuses. Although no adverse effects or complications have been attributed to the use of intra-vaginal nystatin in neonates born to women treated during pregnancy, no similar studies evaluating complications of oral nystatin have been conducted.

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.

Pediatric Use

See **DOSAGE AND ADMINISTRATION** section for pediatric dosing recommendations.

ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Gastrointestinal symptoms including diarrhea, gastrointestinal distress, nausea, vomiting and burning of the mouth have been reported. Hypersensitivity reactions including rash, pruritus, and anaphylactoid reaction have also been reported.

OVERDOSAGE

Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset.

DOSAGE AND ADMINISTRATION

Infants: 2 mL (200,000 units) four times daily (1 mL in each side of mouth).

Pediatric patients and adults: 4 to 6 mL (400,000 to 600,000 units) four times daily (one-half of dose in each side of mouth).

NOTE: Limited clinical studies in neonates, including premature and low-birth weight neonates, indicate that 1 mL (100,000 units) four times daily is effective.

Local treatment should be continued at least 48 hours after perioral symptoms have disappeared and/or cultures returned to normal. It is recommended that the drug be retained in the mouth as long as possible before swallowing.

HOW SUPPLIED

Nystatin Oral Suspension USP, 100,000 units per mL, is available as a yellow, milky, ready-to-use suspension with a cherry-mint flavor in the following sizes:

60 mL bottles (with child-resistant calibrated dropper)

473 mL bottles

A 2 mL calibrated dropper with 1 mL calibrations is provided with the 60 mL container.

SHAKE WELL BEFORE USING.

Storage: Store between 15°-30°C (59°-86°F). PROTECT FROM FREEZING.

Dispense in a tight, light resistant container when dispensing from the original container.

KEEP OUT OF REACH OF CHILDREN.

Manufactured by:

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev. 587:02 08/17

Package/Label Display Panel

AKORN

NDC 50383-587-16

Nystatin Oral Suspension, USP

100,000 units per mL

Rx only

SHAKE WELL BEFORE USING

WARNING- NOT FOR INJECTION

473 mL

NYSTATIN

nystatin suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50383-587
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)	NYSTATIN	100000 [USP'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	YELLOW (yellow, milky)	**Score**	
Shape		**Size**	
Flavor	CHERRY, PEPPERMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-587-66	1 in 1 CARTON	01/27/2012	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:50383-587-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064042	01/27/2012	

Labeler - Hi-Tech Pharmacal Co., Inc. (117696873)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co., Inc.		117696873	MANUFACTURE(50383-587)

Revised: 10/2020 Hi-Tech Pharmacal Co., Inc.