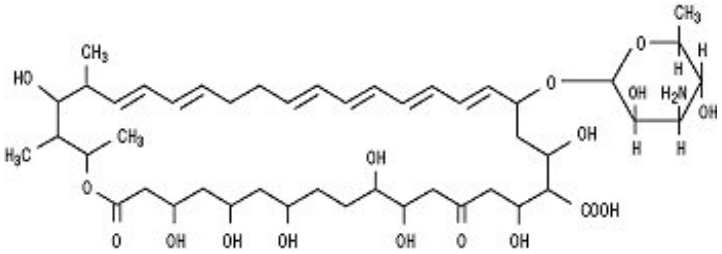
NYSTATIN- nystatin powder
Par Pharmaceutical Inc.

DESCRIPTION

Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces nursei.*

Structural formula:



Nystatin

Nystatin Topical Powder is for dematologic use.

NystatinTopical Powder contains 100,000 USP nystatin units per gram dispersed in talc.

CLINICAL PHARMACOLOGY

Pharmacokinetics

Nystatin is not absorbed from intact skin or mucous membrane.

Microbiology

Nystatin is an antibiotic which is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi, including *Candida albicans, C. parapsilosis, C. tropicalis, C. guilliermondi, C. pseudotropicalis, C. krusei, Torulopsis glabrata, Tricophyton rubrum, T. mentagrophytes.*

Nystatin acts by binding to sterols in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components. On repeated subculturing with increasing levels of nystatin, *Candida albicans* does not develop resistance to nystatin. Generally, resistance to nystatin does not develop during therapy. However, other species of *Candida* (*C. tropicalis, C. guilliermondi, C. krusei, and C. stellatoides*) become quite resistant on treatment with nystatin and simultaneously become cross resistant to amphotericin as well. This resistance is lost when the antibiotic is removed.

Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

INDICATIONS AND USAGE

Nystatin topical powder is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

This topical powder is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nystatin topical powder is contraindicated in patients with a history of hypersensitivity to **any** of its components.

PRECAUTIONS

General

Nystatin topical powder should not be used for the treatment of systemic, oral, intravaginal or ophthalmic infections.

If irritation or sensitization develops, treatment should be discontinued and appropriate measures taken as indicated. It is recommended that KOH smears, cultures, or other diagnostic methods be used to confirm the diagnosis of cutaneous or mucocutaneous candidiasis and to rule out infection caused by other pathogens.

INFORMATION FOR THE PATIENT

Patients using this topical powder should receive the following information and instructions:

1. The patient should be instructed to use this powder as directed (including the replacement of missed doses). This topical powder is not for any disorder other than that for which it is prescribed.
2. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue therapy until the prescribed course of treatment is completed.
3. If symptoms of irritation develop, the patient should be advised to notify the physician promptly.

Laboratory Tests

If there is a lack of therapeutic response, KOH smears, cultures, or other diagnostic methods should be repeated.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or its effects on male or female fertility.

Pregnancy: Teratogenic Effects

Category C. Animal reproduction studies have not been conducted with any nystatin topical preparation. It also is not known whether these preparations can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin topical preparations should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus.

Nursing Mothers

It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is prescribed for a nursing woman.

Pediatric Use

Safety and effectiveness have been established in the pediatric population from birth to 16 years.

(See **DOSAGE AND ADMINISTRATION.**)

ADVERSE REACTIONS

The frequency of adverse events reported in patients using nystatin preparations is less than 0.1%. The more common events that were reported include allergic reactions, burning, itching, rash, eczema, and

pain on application.

(See **PRECAUTIONS: General.**)

DOSAGE AND ADMINISTRATION

Very moist lesions are best treated with the topical dusting powder.

Nystatin Topical Powder

Adults and Pediatric Patients (Neonates and Older):

Apply to candidal lesions two (2) or three (3) times daily until healing is complete. For fungal infection of the feet caused by *Candida* species, the powder should be dusted on the feet, as well as, in all foot wear.

HOW SUPPLIED

Nystatin Topical Powder:

100,000 units nystatin per gram in 15 g (NDC 49884-900-18) plastic squeeze bottles.

100,000 units nystatin per gram in 56.7 g (NDC 44894-900-98) plastic squeeze bottles.

STORAGE

NystatinTopical Powder: Store at 20-25º C (68-77º F) [See USP Controlled Room Temperature]; avoid excessive heat (40º C; 104º F). Keep tightly closed.

Rx Only

Manufactured by:

KALI LABORATORIES, INC.

Somerset, NJ 08873 USA

Distributed by:

PAR PHARMACEUTICAL, INC.

Spring Valley, NY 10977 USA

Issued: 05/03

NYSTATIN

nystatin powder

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:49884-900
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Nystatin (UNII: BDF1O1C72E) (Nystatin - UNII:BDF1O1C72E)		100000 in 1 g

Inactive Ingredients

Ingredient Name	Strength
talc (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49884-900-98	56.7 g in 1 BOTTLE, PLASTIC		
2	NDC:49884-900-18	15 g in 1 BOTTLE, PLASTIC		

Labeler - Par Pharmaceutical Inc.

Revised: 8/2007 Par Pharmaceutical Inc.