NYSTATIN- nystatin powder
Mayne Pharma Inc.

NYSTATIN TOPICAL POWDER, USP

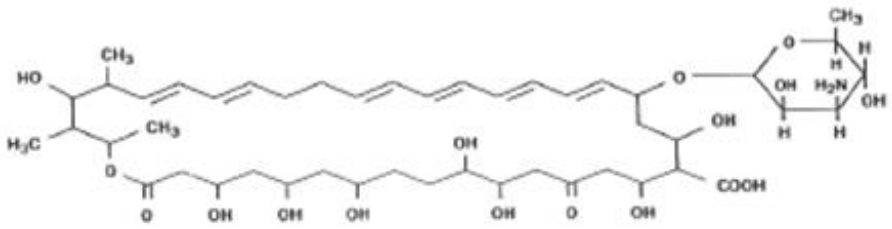
Rx Only

FOR TOPICAL USE ONLY.
NOT FOR OPHTHALMIC USE.

DESCRIPTION

Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces noursei*. The molecular formula for Nystatin is $C_{47}H_{75}NO_{17}$. The molecular weight of Nystatin is 926.1.

Structural formula:



Nystatin topical powder is for dermatologic use.

Nystatin topical 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.

Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria, and associated test methods and quality control standards recognized by FDA for this drug, please see: http://www.fda.gov/STIC.

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.

Nystatin 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 medication should receive the following information and instructions:

1. The patient should be instructed to use this medication as directed (including the replacement of missed doses). This medication 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 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

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 powder 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**.)

Geriatric Use

Clinical studies with nystatin topical powder did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

The frequency of adverse events reported in patients using nystatin topical powder 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.

Adults and Pediatric Patients (Neonates and Older)

Apply to candidal lesions two or three 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, USP is supplied as 100,000 units nystatin per gram in plastic squeeze bottles:

15g (NDC 68308-152-15)
30g (NDC 68308-152-30)
60g (NDC 68308-152-60)

STORAGE

Store at 20°C to 25°C (68°F to 77°F)[see USP Controlled Room Temperature]; avoid excessive heat (40°C/104°F).

Keep tightly closed.

Mayne Pharma Greenville, NC
27834
1-844-825-8500

61207 Rev. 09/2019

PRINCIPAL DISPLAY PANEL - 15 gram Bottle Label

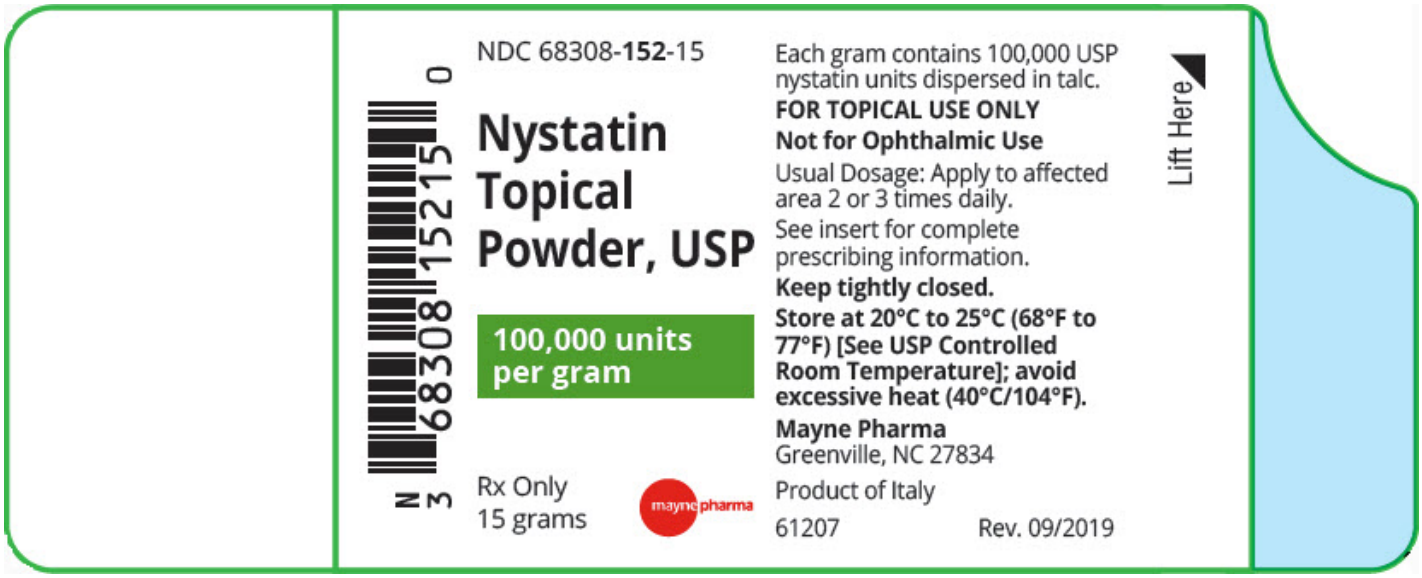
NDC 68308-152-15

Nystatin
Topical
Powder, USP

100,000 units
per gram

Rx Only
15 grams

mayne pharma



NYSTATIN

nystatin powder

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68308-152
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
Talc (UNII: 7SEV7J4R1U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68308-152-15	15 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2004	
2	NDC:68308-152-30	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2004	
3	NDC:68308-152-60	60 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065203	07/15/2004	

Labeler - Mayne Pharma Inc. (867220261)

Establishment

Name	Address	ID/FEI	Business Operations
Mayne Pharma Inc.		867220261	MANUFACTURE(68308-152) , ANALYSIS(68308-152) , LABEL(68308-152) , PACK(68308-152)

Revised: 11/2019 Mayne Pharma Inc.