

**NYSTATIN- nystatin powder**  
**Proficient Rx LP**

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**Rx Only.**  
**Nystatin Topical Powder, USP**

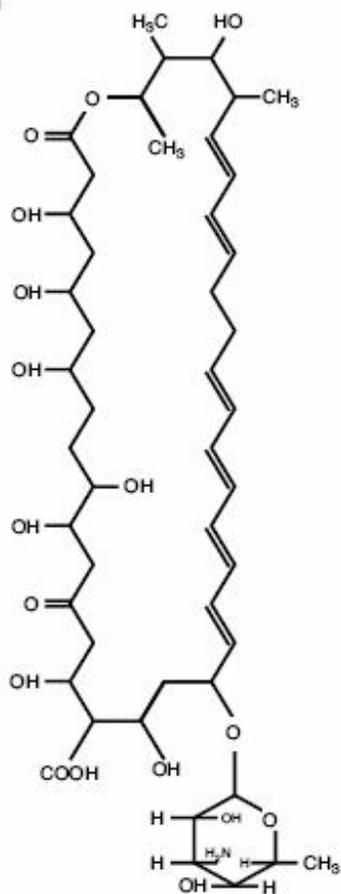
**FOR TOPICAL USE ONLY.**  
**NOT FOR OPHTHALMIC USE.**

**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:



**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. stellatoidea*) 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.

**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 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**).

## **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 is supplied as 100,000 units nystatin per gram in plastic squeeze bottles.

NDC 71205-106-30 for 30 g.

## **STORAGE**

Store at 20° - 25°C (68° - 77°F) and excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat (40°C/104°F). Keep tightly closed. **Keep out of reach of children.**

Manufactured for  
 Vensun Pharmaceuticals, Inc.  
 790 Township Line Rd.  
 Yardley, PA 19067

Rev 01, January 2018

Relabeled By;  
 Proficient RX LP.  
 Thousand Oaks CA 91320

**PRINCIPAL DISPLAY PANEL**

**30g Presentation**

**NDC 71205-106-30**

**Nystatin Topical Powder, USP**

**100,000 USP units per gram**

**30 grams**

**FOR TOPICAL USE ONLY**

**Not for Ophthalmic Use**

**Rx Only**




NDC 71205-106-30

Lot #:00000  
 Exp. 00/00/00  
 SN#MASTER

**RX Only**

**Nystatin 100,000 Units**

**30gm Topical Powder**

Each gram contains: 100,000 USP Nystatin units dispersed in talc.

*See package insert.*

**FOR TOPICAL USE ONLY**

Product ID: SN010630

Mfr. For: Vensun Pharmaceuticals, Inc 790 Township Line Rd. Yardley, PA 19067.  
 Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Relabeled By: Proficient Rx LP  
 Thousand Oaks, CA 91320

Nystatin 100,000 Units 30gm Topical Powder Lot #:00000 NDC 71205-106-30	SN#MASTER Exp:00/00/00
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**NYSTATIN**

nystatin powder

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71205-106(NDC:42543-052)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)		NYSTATIN	100000 [USPU] in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
TALC (UNII: 7SEV7J4R1U)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71205-106-30	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2018	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA		ANDA065175	09/01/2014	

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-106)

Revised: 10/2019

Proficient Rx LP