

NYSTATIN- nystatin ointment ointment Proficient Rx LP

NYSTATIN OINTMENT, USP

100,000 USP Nystatin Units Per Gram

For Topical Use Only. Not For Ophthalmic Use.

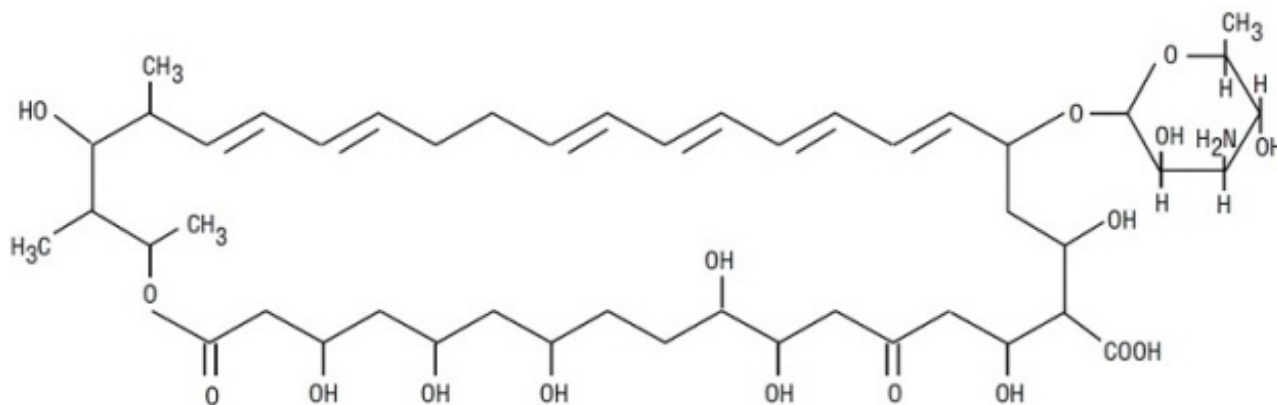
Rx Only

DESCRIPTION

Nystatin Ointment, USP is for dermatologic use. Nystatin Ointment, USP for topical use only, contains 100,000 USP nystatin units per gram, in a white petrolatum base.

Nystatin is a polyene antifungal antibiotic drug obtained from *Streptomyces noursei*.

The structural formula is as follows:



Molecular Weight 926.13

Molecular Formula C₄₇H₇₅NO₁₇

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*, *Trichophyton 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 concentrations 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 Ointment, USP is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

Nystatin Ointment, USP is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nystatin Ointment is contraindicated in patients with a history of hypersensitivity to any of their components.

PRECAUTIONS

General

Nystatin Ointment 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 these medications should receive the following information and instructions:

1. The patient should be instructed to use these medications as directed (including the replacement of missed doses). These medications are not for any disorder other than that for which they are 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 Ointment 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.**)

To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Nystatin Ointment

Adults and Pediatric Patients (Neonates and Older):

Apply liberally to affected areas twice daily or as indicated until healing is complete.

HOW SUPPLIED

Nystatin Ointment, USP (100,000 USP Nystatin Units per gram) is a light yellow to yellow ointment available as follows:

NDC 71205-437-15 15 gram tube

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Distributed by:

Cosette Pharmaceuticals, Inc.
South Plainfield, NJ 07080

Relabeled by:

Proficient Rx LP
Thousand Oaks, CA 91320

8-0686CPLNC2

Rev: 03/2021

VC7553

PRINCIPAL DISPLAY PANEL

NDC 71205-437-15



Nystatin Ointment, USP

100,000 USP Nystatin Units Per Gram

15 g

Rx only

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.

<p>Scan Here</p> 		<p>NDC 71205-437-15</p>	<p>Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320</p>
<p>Nystatin 100,000 Units</p>		<p>RX Only</p>	
<p>15 g Ointment</p>		<p>Nystatin 100,000 Units 15 g Ointment SN# MASTER Lot #:00000 Exp:00/00/00 NDC 71205-437-15</p>	
<p>Each gram contains: 100,000 USP Nystatin Units in a white petrolatum base.</p>		<p>Nystatin 100,000 Units 15 g Ointment SN# MASTER Lot #:00000 Exp:00/00/00 NDC 71205-437-15</p>	
<p>See package insert.</p>	<p>FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.</p>		<p>Nystatin 100,000 Units 15 g Ointment SN#MASTER Lot #:00000 Exp:00/00/00 NDC 71205-437-15</p>
<p>Product ID: SN043715</p>		<p>GTIN: 00371205437152 SN# MASTER Exp. 00/00/00 Lot #:00000</p>	
<p>Mfr. By: G&W Laboratories, Inc. South Plainfield, NJ 07080</p>		<p>Keep medication out of the reach of children</p>	
<p>Store at 20°-25°C (68°-77°F)</p>			

NYSTATIN

nystatin ointment ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71205-437(NDC:0713-0686)
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
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-437-15	1 in 1 CARTON	03/19/2020	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209114	10/06/2017	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-437)

Revised: 3/2020

Proficient Rx LP