

NYSTATIN- nystatin ointment
RPK Pharmaceuticals, Inc.

Nystatin Ointment USP

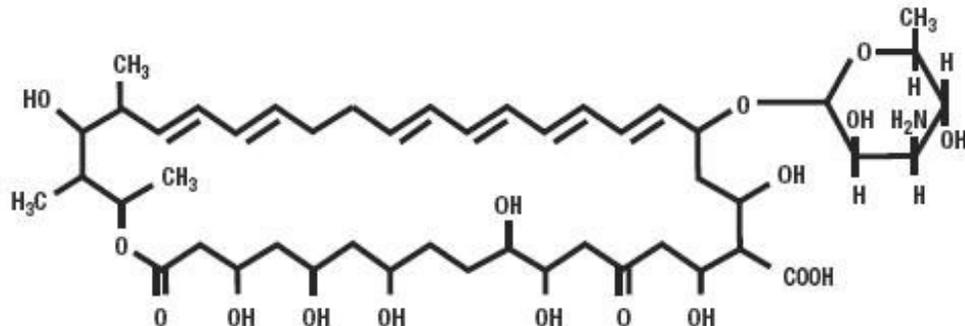
For Dermatologic Use Only

Not for Ophthalmic Use

Rx Only

DESCRIPTION

Nystatin Ointment USP for topical use only, contains 100,000 USP Nystatin units per gram, in an ointment base of light mineral oil and white petrolatum. The structural formula is as follows:



Molecular Weight 926.13

Molecular Formula $C_{47}H_{75}NO_{17}$

CLINICAL PHARMACOLOGY

Nystatin is an antifungal antibiotic which is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. It probably 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 a polyene antibiotic that is obtained from *Streptomyces noursei*, and is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous, oral and intestinal infections caused by *Candida* [Monilia]*albicans* and other *Candida* species. It exhibits no appreciable activity against bacteria.

Nystatin Ointment USP provides specific therapy for all localized forms of candidiasis. Symptomatic relief is rapid, often occurring within 24 to 72 hours after the initiation of treatment. Cure is effected both clinically and mycologically in most cases of localized candidiasis.

INDICATIONS AND USAGE

Nystatin Ointment USP is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* [*Monilia*]*albicans* and other *Candida* species.

CONTRAINDICATIONS

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

PRECAUTIONS

Should a reaction of hypersensitivity occur, the drug should be immediately withdrawn and appropriate measures taken.

This preparation is not for ophthalmic use.

ADVERSE REACTIONS

Nystatin Ointment USP is virtually non-toxic and nonsensitizing and is well tolerated by all age groups including debilitated infants, even on prolonged administration. If irritation on topical application should occur, discontinue medication.

DOSAGE AND ADMINISTRATION

Nystatin Ointment USP should be applied liberally to affected areas twice a day or as indicated until healing is complete. Nystatin cream is usually preferred to nystatin ointment in candidiasis involving intertriginous areas; very moist lesions, however, are best treated with nystatin topical powder.

This preparation does not stain skin or mucous membranes and provides a simple, convenient means of treatment.

HOW SUPPLIED

Product: 53002-8220

NDC: 53002-8220-1 15 g in a TUBE

Nystatin Topical Ointment 100,000 U/GM

NDC# 53002-8220-1
 LIST# 45802-048-35
**NYSTATIN TOPICAL
 OINTMENT 100,000 U/GM**
 15 Gm Tube
 LOT# 1827014-002
 EXPI DATE: 04-30-2020
 Shape & Color Markings

Rx only

EACH GIM CONTAINS:
 NYSTATIN 100,000UM
 (See tube for a list of
 inactive ingredients.)

IMPORTED BY: RPK PHARMACEUTICALS, INC.
 8000 S. PERDUE BOULEVARD, SUITE 100
 DIST. BY: Pharmadix, Union City, CA 94587

15 Gm Tube PATIENT NAME: _____
NYSTATIN 100,000 U/GM OINTMENT
 PEREGO Ref# 182870141000 ITEM# 8220 822.43

**APPLY TO AFFECTED
 AREA TWICE A DAY
 OR AS DIRECTED.**

CLINIC NAME GOES HERE
 Prescriber Name _____
 Date Prescribed _____

IMPORTANT: THIS DRUG IS AN
 ANTI-FUNGAL AGENT FOR EXTERNAL
 USE ONLY. USE AS DIRECTED AND
 FOR THE FULL LENGTH OF TREAT-
 MENT PRESCRIBED.



182870141000 ITEM# 8220

APP AFF AREA BID OR QD
 LOT# 18264-002 EXP 04-30-2020
 Ref# 182870141 000 FCJ# 8220
 15 Gm NYSTATIN 100,000 U/GM OINTMENT

**NYSTATIN TOPICAL
 OINTMENT 100,000 U/GM**
 15 Gm Tube

BILLING NDC# 45802-048-35 DISCARD BY 04-30-2020
 Ref# 182870141 000 NDC# 53002-8220-1
 15 Gm NYSTATIN 100,000 U/GM OINTMENT Ref# 182870141 000

BILLING NDC# 45802-048-35
 Ref# 182870141 000
 15 Gm NYSTATIN 100,000 U/GM OINTMENT

BILLING NDC# 45802-048-35
 Ref# 182870141 000
 15 Gm NYSTATIN 100,000 U/GM OINTMENT

Clinic Name Here

NYSTATIN

nystatin ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53002-8220(NDC:45802-048)
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
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53002-8220-1	15 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062472	09/15/2006	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-8220) , REPACK(53002-8220)

Revised: 6/2023

RPK Pharmaceuticals, Inc.