

**NYSTATIN- nystatin ointment**  
**Proficient Rx LP**

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**NYSTATIN OINTMENT USP**  
**(100,000 units/g)**

**Rx Only**

**DESCRIPTION**

Each gram of Nystatin Ointment USP contains 100,000 units of nystatin in a white petrolatum base.

**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 of undetermined structural formula 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 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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.

**ADVERSE REACTIONS**

Nystatin is virtually nontoxic 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 the affected areas twice a day or as indicated until healing is complete. The ointment does not stain the skin or mucous membranes and it provides a simple, convenient means of treatment.

## **HOW SUPPLIED**

Nystatin Ointment USP 100,000 units/g

15 g tube (0.53 oz)

Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.

Distributed by:

Actavis Pharma, Inc.

Parsippany, NJ 07054 USA

FORM NO. 0166

Rev. 10/19

VC2752

Relabeled By:

Proficient Rx LP

Thousand Oaks, CA 91320

## **Package/Label Display Panel**



Scan Here



NDC 63187-464-15

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

**RX Only**

Nystatin 100,000 Units  
15g (0.53 oz) Ointment  
Lot #:00000 SN# MASTER  
NDC 63187-464-15 Exp:00/00/00

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NDC 63187-464-15 Exp:00/00/00



GTIN: 00363187464158  
SN# MASTER  
Exp. 00/00/00  
Lot #:00000



# Nystatin 100,000 Units

## 15g (0.53 oz) Ointment

Each gram contains: 100,000 units of nystatin USP in a white petrolatum base.

See package insert

**For External Use Only  
Not for Ophthalmic Use**

Product ID: RN046415

Dist. By: Actavis Pharma, Inc. Parsippany, NJ 07054 USA

Store at controlled room temperature 15°-30°C (59°-86°F). Do not freeze.

Keep medication out of the reach of children

### NYSTATIN

nystatin ointment

#### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:63187-464(NDC:0472-0166)
<b>Route of Administration</b>	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:63187-464-15	1 in 1 CARTON	01/01/2019	
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	ANDA062840	09/03/2002	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-464) , RELABEL(63187-464)

Revised: 10/2022

Proficient Rx LP