

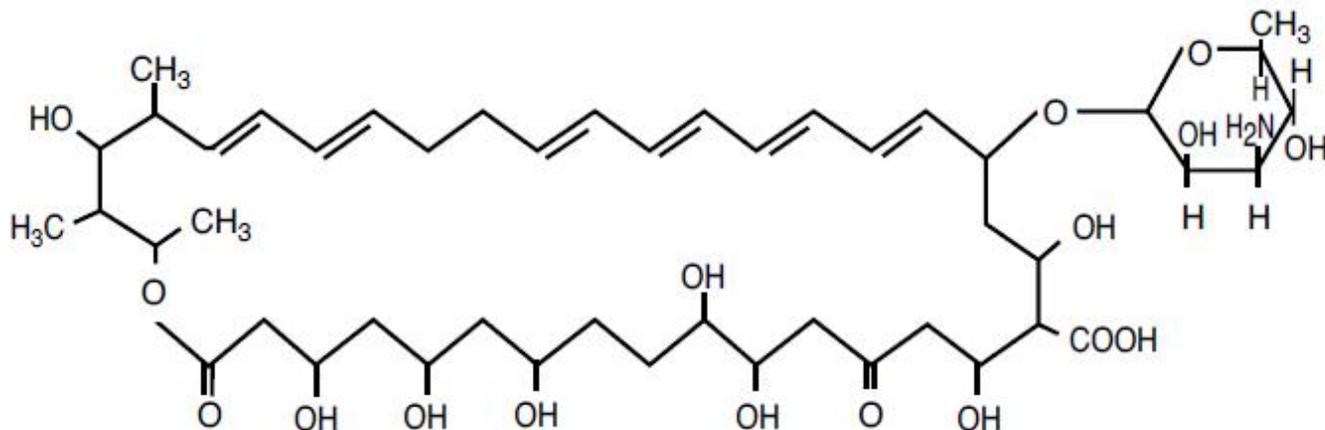
**NYSTATIN- nystatin ointment**  
**Rebel Distributors Corp**

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**NYSTATIN OINTMENT USP**

R<sub>x</sub> only

**DESCRIPTION**

Nystatin Ointment USP, for topical use only, contains 100,000 USP Nystatin Units per gram, in a polyethylene and mineral oil base. The structural formula is as follows:



Molecular Weight 926.13

Molecular Formula C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub>

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

**CONTRAINDICATIONS**

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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.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

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

NDC 42254-284-15 15 gram tube

Store at controlled room temperature 15°- 30°C (59°-86°F).

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.

Melville, New York 11747

I20715H

R08/11

#21

Repackaged by:

REBEL DISTRIBUTORS CORP.

Thousand Oaks, CA 91320

## **PRINCIPAL DISPLAY PANEL**

Peel	Peel	 <p style="font-size: 12px; margin: 0;">NDC 42254-284-15</p> <h2 style="margin: 0;">Nystatin 100,000 Units/gm</h2> <h3 style="margin: 0;">15gm Ointment</h3> <p style="font-size: 10px; margin: 5px 0;">Each gram contains: 100,000 USP Nystatin units per gram in a Polyethylene and mineral oil base.</p> <p style="font-size: 10px; margin: 0;"><i>See package insert.</i></p> <div style="border: 1px solid black; display: inline-block; padding: 2px 5px; margin: 5px 0;">Product ID: SN028415</div>	Peel	Peel
Nystatin 100,000 Units/gm 15gm Ointment Rx# Master Lot #:00000 Exp. Date: 00/00/00 NDC 42254-284-15 AWP:\$33.60 Nystatin 100,000 Units/gm 15gm Ointment Rx# Master Lot #:00000 Exp. Date: 00/00/00 NDC 42254-284-15 AWP:\$33.60	Lot #:00000 Exp. 00/00/00             	SN028415                   	Nystatin 100,000 Units/gm 15gm Ointment Rx# Master Lot #:00000 Exp. Date: 00/00/00 NDC 42254-284-15 AWP:\$33.60 Nystatin 100,000 Units/gm 15gm Ointment Rx# Master Lot #:00000 Exp. Date: 00/00/00 NDC 42254-284-15 AWP:\$33.60	

RX#Master    RX Only    Mfr. By: E. Fougera & Co. a division of Nycomed US Inc., Melville, New York 11747

Distributed by: Physician Partner, Thousand Oaks, CA 91320 [www.physicianpartner.com](http://www.physicianpartner.com)  
Store at controlled room temperature 15°-30° C (59°-86° F)    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:42254-284(NDC:0168-0007)
<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
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
Mineral Oil (UNII: T5L8T28FGP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:42254-284-15	15 g in 1 TUBE		
<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	ANDA062124	09/23/1982		

**Labeler** - Rebel Distributors Corp (118802834)

**Registrant** - PSS World Medical, Inc. (101822862)

**Establishment**

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-284)

**Establishment**

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-284)

**Establishment**

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-284) , REPACK(42254-284)

**Establishment**

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-284) , REPACK(42254-284)

**Establishment**

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-284)

**Establishment**

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-284) , REPACK(42254-284)