

## NYSTATIN- nystatin ointment

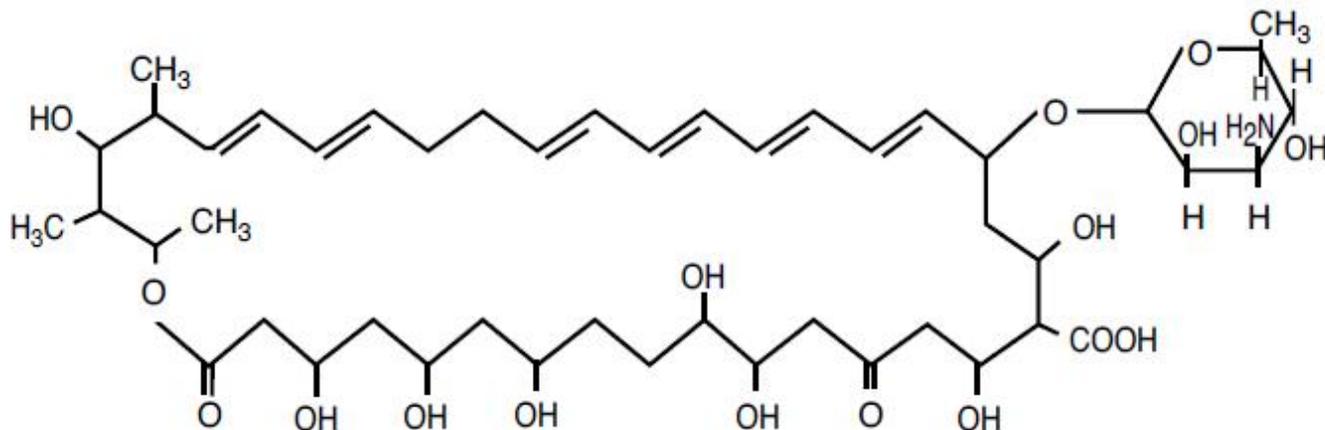
E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc.

### 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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.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 0168-0007-15 15 gram tube

NDC 0168-0007-30 30 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

## **PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CONTAINER**

NDC 0168-0007-15

FOUGERA®

### **NYSTATIN OINTMENT USP**

100,000 USP Nystatin Units Per Gram

For Topical Use Only.

Not for Ophthalmic Use.

**Rx** only

CONTAINS: 100,000 USP

Nystatin Units per gram,

in a polyethylene and

mineral oil base.

**NET WT 15 grams**



**PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CARTON**

NDC 0168-0007-15

**FOUGERA®** Rx only

**NYSTATIN OINTMENT USP**

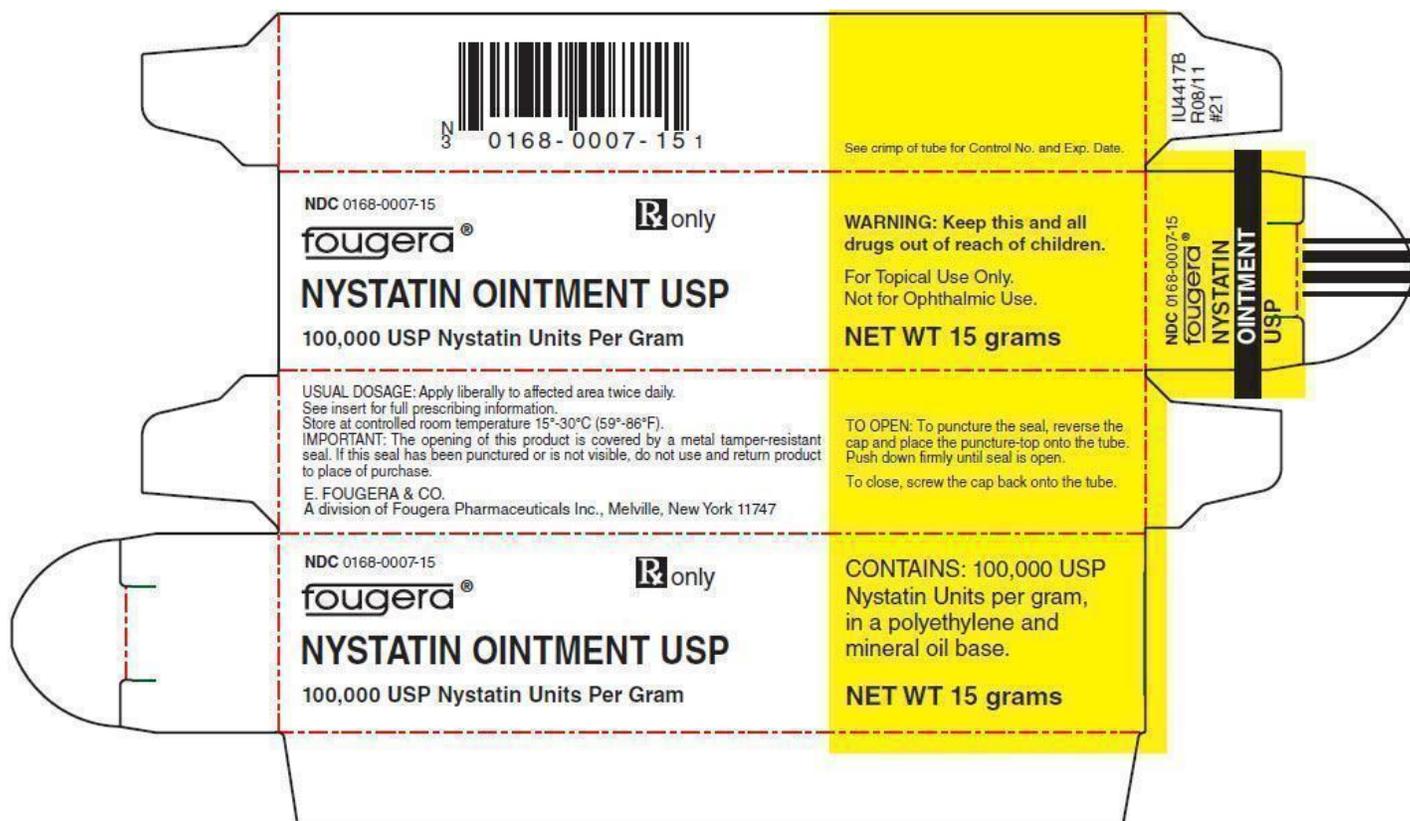
100,000 USP Nystatin Units Per Gram

**WARNING: Keep this and all  
drugs out of reach of children.**

For Topical Use Only.

Not for Ophthalmic Use.

**NET WT 15 grams**



## NYSTATIN

nystatin ointment

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	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:0168-0007-15	15 g in 1 TUBE		
2	NDC:0168-0007-30	30 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062124	09/23/1982	

**Labeler** - E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc. (043838424)

## Establishment

Name	Address	ID/FEI	Business Operations
Fougera Pharmaceuticals Inc.		174491316	MANUFACTURE

## Establishment

Name	Address	ID/FEI	Business Operations
Fougera Pharmaceuticals Inc.		043838424	ANALYSIS

Revised: 4/2012

E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc.