

NYSTATIN- nystatin ointment
Aidarex Pharmaceuticals LLC

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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.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

Manufactured by:

Actavis Mid Atlantic LLC

1877 Kawai Road

Lincolnton, NC 28092 USA

FORM NO. 0166

Repackaged By :

Aidarex Pharmaceuticals LLC,

Corona, CA 92880

Rev. 1/06

VC2752

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP 15-30C (59-86F)	Packaged and Distributed by: AIDAREX PHARMACEUTICALS LLC.	NYSTATIN OINT. 15 G 100,000U	PEEL HERE	
	NYSTATIN OINT.	NDC: 53217-0022-01 RX 1000966176		PATIENT LOG
	100,000U	NYSTATIN OINT. 15 G 100,000U		
	15 G	GENERIC FOR : MYCOSTATIN NDC: 53217-0022-01 APPLY _____ TIMES DAILY APLIQUE _____ VECES AL DIA MFG: ACTAVIS MIDATLANTIC LLC LINCOLNTON, NC 28092		NDC: 53217-0022-01 RX 1000966176
EACH GRAM CONTAINS THE FOLLOWING ACTIVE INGREDIENTS: NYSTATIN..... 100,000 Units	NYSTATIN OINT. 15 G 100,000U NDC: 53217-0022-01 RX 1000966176	BILL		
		NYSTATIN OINT. 15 G 100,000U NDC: 53217-0022-01 RX 1000966176	PEEL HERE	

NYSTATIN

nystatin ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53217-022(NDC:0472-0166)
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:53217-022-01	15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062840	09/03/2002	

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 10/2013

Aidarex Pharmaceuticals LLC