NYSTATIN- nystatin ointment
Actavis Pharma, Inc.

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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.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 is available as follows:

15 g tube (0.53 oz) NDC 0472-0166-15

30 g tube (1.1 oz) NDC 0472-0166-30

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

Manufactured For:

Teva Pharmaceuticals

Parsippany, NJ 07054

Rev. B 6/2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 0472-0166-15

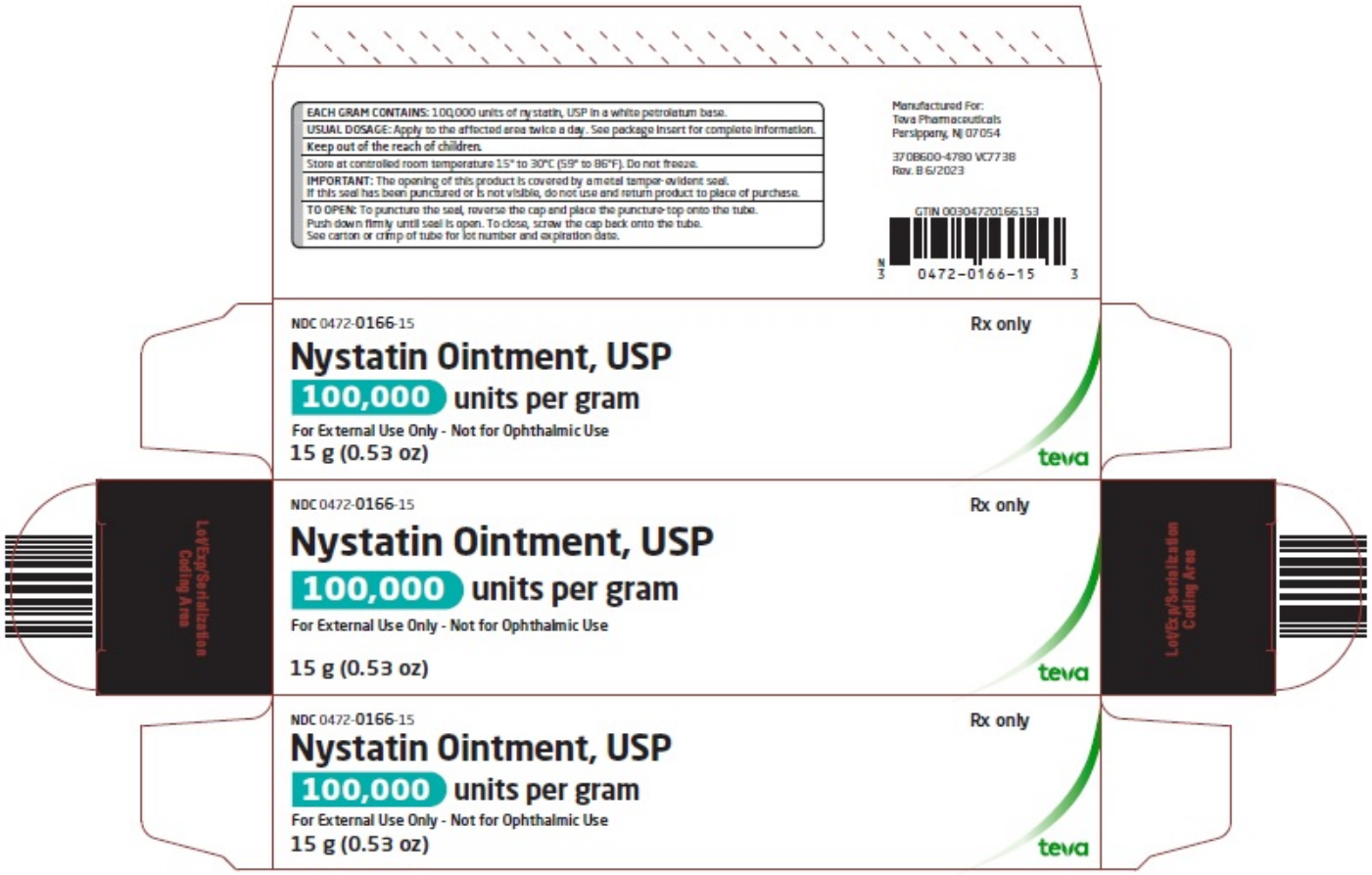
Nystatin Ointment, USP

100,000 units per gram

Rx only

For External Use Only - Not for Ophthalmic Use

15 g (0.53 oz)



NYSTATIN

nystatin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	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:0472-0166-15	1 in 1 CARTON	09/03/2002	

1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0472-0166-30	1 in 1 CARTON	09/03/2002	
2		30 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 - Actavis Pharma, Inc. (119723554)

Revised: 6/2023 Actavis Pharma, Inc.