NYSTATIN- nystatin ointment
Padagis Israel Pharmaceuticals Ltd

Nystatin Ointment USP

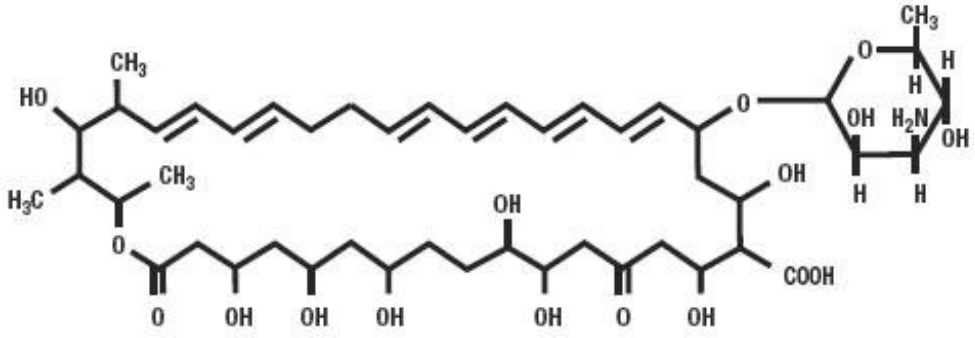
For Dermatologic Use Only

Not for Ophthalmic Use

Rx Only

DESCRIPTION

Nystatin Ointment USP for topical use only, contains 100,000 USP Nystatin units per gram, in an ointment base of light mineral oil and white petrolatum. The structural formula is as follows:



Molecular Weight 926.13

Molecular Formula $C_{47}H_{75}NO_{17}$

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Should a reaction of hypersensitivity occur, the drug should be immediately withdrawn and appropriate measures taken.

This preparation is not for ophthalmic use.

ADVERSE REACTIONS

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

15 g tube (NDC 45802-**048**-35)

30 g tube (NDC 45802-**048**-11)

STORAGE

Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].

Manufactured by Padagis®
Yeruham, Israel

www.padagis.com

Rev 01-23

7K600 RC PH1

Principal Display Panel

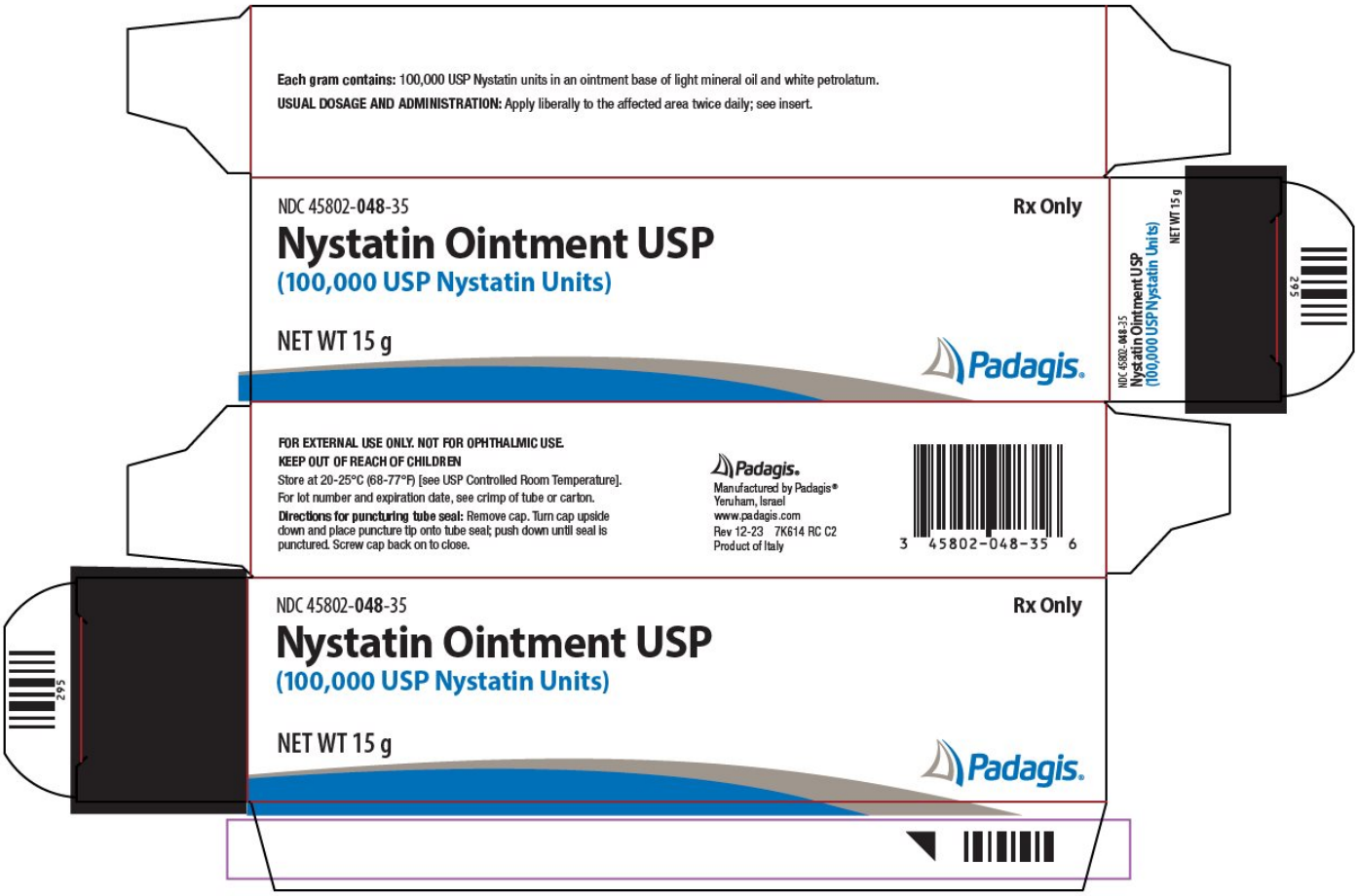
NDC 45802-048-35

Rx Only

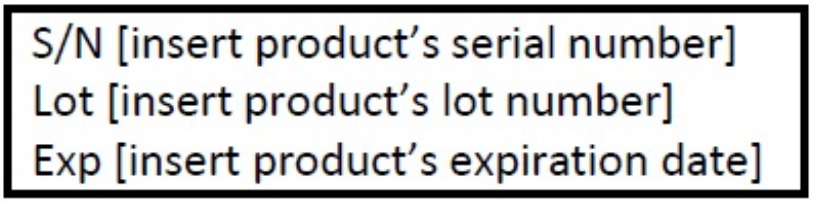
Nystatin Ointment USP

(100,000 USP Nystatin Units)

NET WT 30 g



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.



NYSTATIN

nystatin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45802-048
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**
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-048-35	1 in 1 CARTON	09/15/2006	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:45802-048-11	1 in 1 CARTON	11/08/2006	
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	ANDA062472	09/15/2006	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 1/2025

Padagis Israel Pharmaceuticals Ltd