NYSTATIN- nystatin ointment
Bryant Ranch Prepack

Nystatin Ointment USP

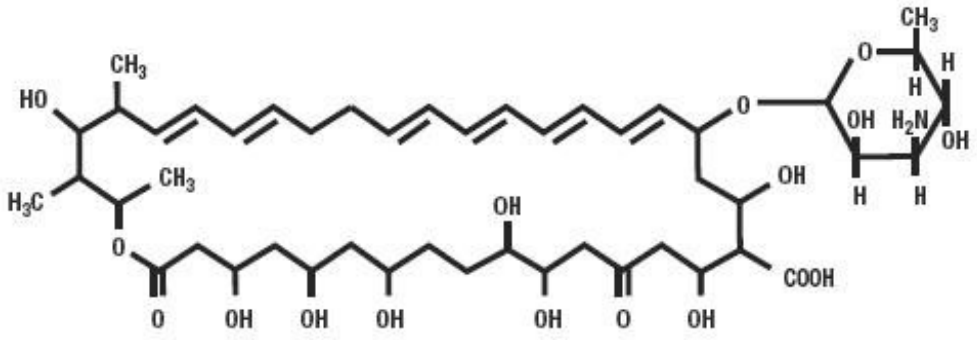
For Dermatologic Use Only

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Should a reaction of hypersensitivity occur, the drug should be immediately withdrawn and appropriate measures taken.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

- NDC 72162-2333-2: 15 g in a TUBE
- NDC 72162-2333-3: 30 g in a TUBE

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

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Nystatin Ointment USP (100,000 USP Nystatin Units)

Each gram contains: 100,000 USP Nystatin units in an ointment base of light mineral oil and white petrolatum.

For external use only. Not for ophthalmic use. Keep out of reach of children.

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

USUAL DOSAGE AND ADMINISTRATION: Apply liberally to the affected area twice daily; scan Package Insert QR Code.

Package Insert

NDC 72162-2333-2

Nystatin Ointment USP (100,000 USP Nystatin Units)

100,000 Units

BRP PHARMACEUTICALS

Rx only

NET WT 15 g

Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504 USA

Manufactured by:
Padagis

Extended Label

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube seal; push down until seal is punctured. Screw cap back on to close.

NYSTATIN

nystatin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72162-2333(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:72162-2333-2	1 in 1 CARTON	06/18/2024	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72162-2333-3	1 in 1 CARTON	06/18/2024	
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 - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2333) , RELABEL(72162-2333)

Revised: 4/2025 Bryant Ranch Prepack