NYSTATIN- nystatin cream
Rebel Distributors Corp

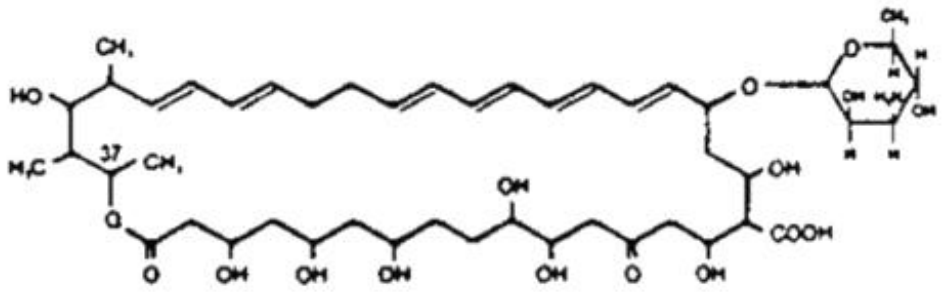
Nystatin
Cream USP, 100,000 units per gram

Rx only

DESCRIPTION

Nystatin Cream is for dermatologic use.

Nystatin is a polyene antimycotic obtained from *Streptomyces noursei*. It is a yellow to light tan powder with a cereal-like odor, very soluble in water, and slightly to sparingly soluble in alcohol. Structural formula:



$C_{47}H_{75}NO_{17}$ MW = 926.13

Nystatin Cream contains the antifungal antibiotic nystatin at a concentration of 100,000 USP Nystatin Units per gram in an aqueous, perfumed cream base containing purified water, propylene glycol, methylparaben, propylparaben, white petrolatum, glyceryl monostearate, polyethylene glycol 400 monostearate, ceteareth-15, medical antifoam AF emulsion, aluminum hydroxide gel, titanium dioxide, sorbitol solution, and, if necessary, sodium hydroxide for pH adjustment.

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 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 Cream is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* (Monilia) *albicans* and other Candida species.

CONTRAINDICATIONS

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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.

Nystatin Cream is not for ophthalmic use.

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 Cream should be applied liberally to affected areas twice daily 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.

HOW SUPPLIED

Nystatin Cream is a smooth yellow cream with a characteristic perfume odor.

Nystatin Cream is supplied in 15g (NDC 21695-761-15) and 30g (NDC 21695-761-30) tubes providing 100,000 USP Nystatin Units per gram.

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

Mfd. by: Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1

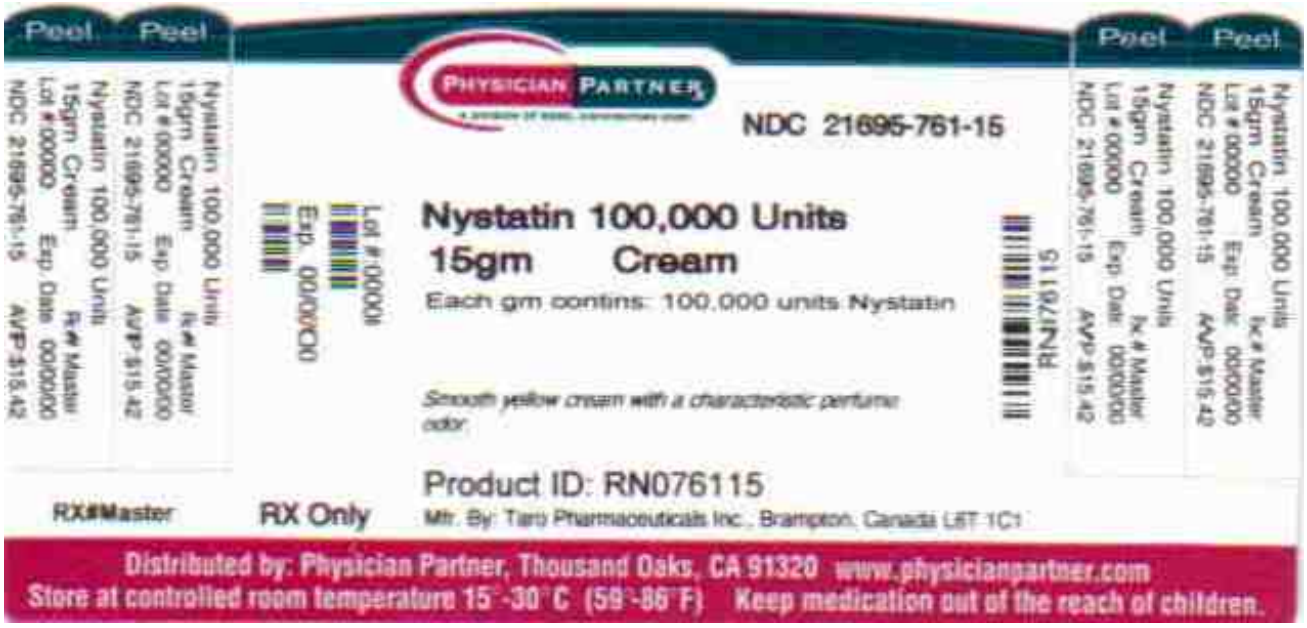
Dist. by: **Taro Pharmaceuticals U.S.A., Inc.**
Hawthorne, NY 10532

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

Principal Display Panel



NYSTATIN

nystatin cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-761(NDC:51672-1289)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Nystatin (UNII: BDF1O1C72E) (Nystatin - UNII:BDF1O1C72E)	Nystatin	100000 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
propylene glycol (UNII: 6DC9Q167V3)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
glyceryl monostearate (UNII: 230OU9XXE4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
ALGELDRATE (UNII: 03J11K103C)	
titanium dioxide (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
sodium hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-761-15	1 in 1 CARTON		
1		15 g in 1 TUBE		
2	NDC:21695-761-30	1 in 1 CARTON		
2		30 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064022	01/29/1993	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 10/2010 Rebel Distributors Corp