NYSTATIN- nystatin cream
Proficient Rx LP

NYSTATIN CREAM USP

(100,000 units/g)

Rx Only

DESCRIPTION

EACH GRAM OF NYSTATIN CREAM USP CONTAINS: 100,000 units in an aqueous cream base of aluminum hydroxide gel, cetearyl alcohol (and) ceteareth-20, citric acid, glyceryl stearate, methylparaben, polyoxyl 40 stearate, propylene glycol, propylparaben, purified water, sodium citrate, sorbic acid, sorbitol solution, titanium dioxide and white petrolatum.

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

CONTRAINDICATIONS

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Should a reaction of hypersensitivity occur the drug should be immediately withdrawn and appropriate measures taken.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

The cream does not stain the skin or mucous membranes and it provides a simple, convenient means of treatment.

HOW SUPPLIED

Nystatin Cream USP 100,000 units/g

15 g tube (0.53 oz)

Store at controlled room temperature 15°-30°C (59°-86°F). Avoid exposure to excessive heat, 40°C (104°F).

Manufactured by:

Actavis Mid Atlantic LLC

1877 Kawai Road

Lincolnton, NC 28092 USA

FORM NO. 0163

Rev. 1/06

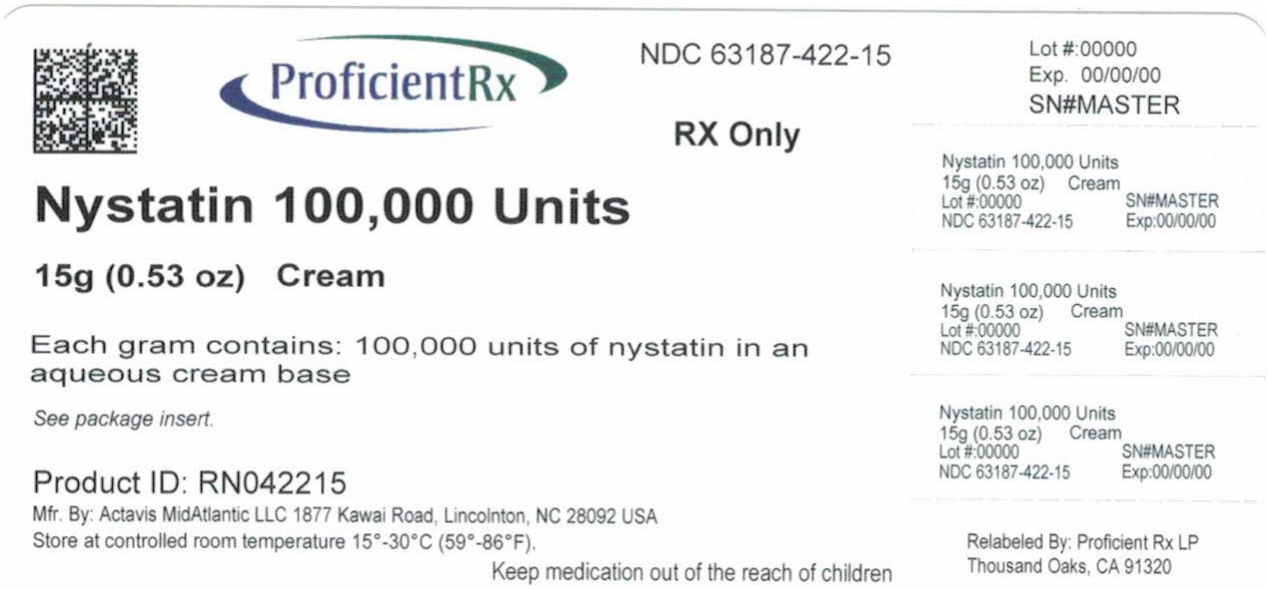
VC2751

Repackaged by:

Proficient Rx LP

Thousand Oaks, CA 91320

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NYSTATIN

nystatin cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63187-422(NDC:0472-0163)
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**
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PETROLATUM (UNII: 4T6H12BN9U)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63187-422-15	1 in 1 CARTON	01/01/2019	
1		15 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	ANDA062949	07/21/2010	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations

Proficient Rx LP		079502574	REPACK(63187-422) , RELABEL(63187-422)