NYSTATIN- nystatin cream
Taro Pharmaceuticals U.S.A., Inc.

Nystatin
Cream USP, 100,000 units per gram

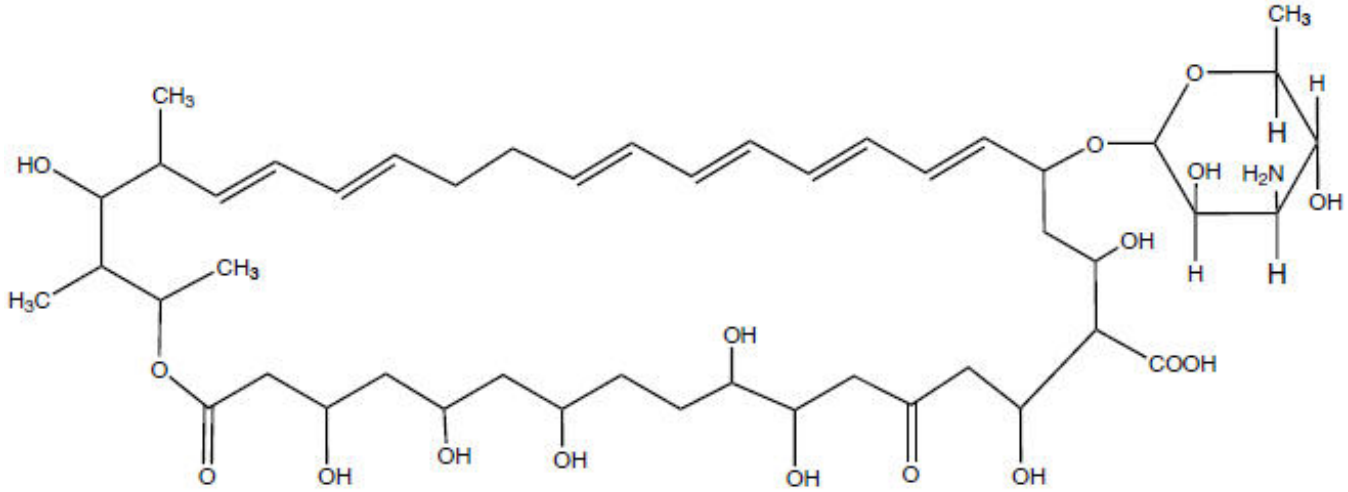
Rx only

FOR TOPICAL USE ONLY • NOT FOR OPHTHALMIC USE

DESCRIPTION

Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces nursei.*

Structural formula:



$C_{47}H_{75}NO_{17}$ Molecular Weight: 926.13

Nystatin cream is for dermatologic use.

Nystatin cream for topical use, contains 100,000 USP nystatin units per gram in an aqueous, perfumed cream base containing aluminum hydroxide gel, ceteareth-15, glyceryl monostearate, polyethylene glycol 400 monostearate, propylene glycol, purified water, simethicone emulsion, sorbitol solution, titanium dioxide, white petrolatum, with methylparaben and propylparaben as preservatives and, if necessary, sodium hydroxide for pH adjustment.

CLINICAL PHARMACOLOGY

Pharmacokinetics

Nystatin is not absorbed from intact skin or mucous membrane.

Microbiology

Nystatin is an antibiotic which is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi, including *Candida albicans, C. parapsilosis, C. tropicalis, C. guilliermondi, C. pseudotropicalis, C. krusei, Torulopsis glabrata, Tricophyton rubrum, T. mentagrophytes.* Nystatin acts by binding to sterols in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components. On repeated subculturing with increasing levels of nystatin, *Candida albicans* does not develop resistance to nystatin. Generally,

resistance to nystatin does not develop during therapy. However, other species of *Candida (C. tropicalis, C. guilliermondi, C. krusei, and C. stellatoides)* become quite resistant on treatment with nystatin and simultaneously become cross resistant to amphotericin as well. This resistance is lost when the antibiotic is removed. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

INDICATIONS AND USAGE

Nystatin cream is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

This cream is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nystatin cream is contraindicated in patients with a history of hypersensitivity to any of its components.

PRECAUTIONS

General

Nystatin cream should not be used for the treatment of systemic, oral, intravaginal or ophthalmic infections.

If irritation or sensitization develops, treatment should be discontinued and appropriate measures taken as indicated. It is recommended that KOH smears, cultures, or other diagnostic methods be used to confirm the diagnosis of cutaneous or mucocutaneous candidiasis and to rule out infection caused by other pathogens.

INFORMATION FOR THE PATIENT

Patients using this medication should receive the following information and instructions:

1. The patient should be instructed to use this medication as directed (including the replacement of missed doses). This medication is not for any disorder other than that for which it is prescribed.
2. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue therapy until the prescribed course of treatment is completed.
3. If symptoms of irritation develop, the patient should be advised to notify the physician promptly.

Laboratory Tests

If there is a lack of therapeutic response, KOH smears, cultures, or other diagnostic methods should be repeated.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or the effects on male or female fertility.

Pregnancy

Teratogenic Effects

Category C

Animal reproduction studies have not been conducted with any nystatin cream. It also is not known whether this cream can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin cream should be prescribed for a pregnant woman only if the potential benefit to the

mother outweighs the potential risk to the fetus.

Nursing Mothers

It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is prescribed for a nursing woman.

Pediatric Use

Safety and effectiveness have been established in the pediatric population from birth to 16 years.

(See **DOSAGE AND ADMINISTRATION**.)

Geriatric Use

Clinical studies with nystatin cream did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

The frequency of adverse events reported in patients using nystatin cream is less than 0.1%. The more common events that were reported include allergic reactions, burning, itching, rash, eczema, and pain on application.

(See **PRECAUTIONS: General**.)

DOSAGE AND ADMINISTRATION

Adults and Pediatric Patients (Neonates and Older)

Apply liberally to affected areas twice daily or as indicated until healing is complete.

HOW SUPPLIED

Nystatin Cream USP is a smooth yellow to light green cream with a characteristic perfume odor.

Nystatin Cream USP is supplied in 15 g (NDC 51672-1289-1) and 30 g (NDC 51672-1289-2) tubes providing 100,000 USP Nystatin Units per gram.

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

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

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

Revised: August, 2010

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107

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-1289-2

30 g

Nystatin
Cream USP, 100,000 units per gram

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

Rx only

Keep this and all medications out of the reach of children.

TARO

NYSTATIN

nystatin cream

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

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)	
glyceryl monostearate (UNII: 230OU9XXE4)	

ceteareth-15 (UNII: 867H4YOZ8Z)	
water (UNII: 059QF0KO0R)	
propylene glycol (UNII: 6DC9Q167V3)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
titanium dioxide (UNII: 15FIX9V2JP)	
algeldrate (UNII: 03J11K103C)	
sorbitol (UNII: 506T60A25R)	
sodium hydroxide (UNII: 55X04QC32I)	

Product Characteristics

Color	YELLOW (smooth yellow to light green)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-1289-1	1 in 1 CARTON		
1		15 g in 1 TUBE		
2	NDC:51672-1289-2	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	01/28/1993	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-1289)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-1289)