NYSTATIN - nystatin cream
Macleods Pharmaceuticals Limited

Nystatin Cream,USP, 100,000 units per gram

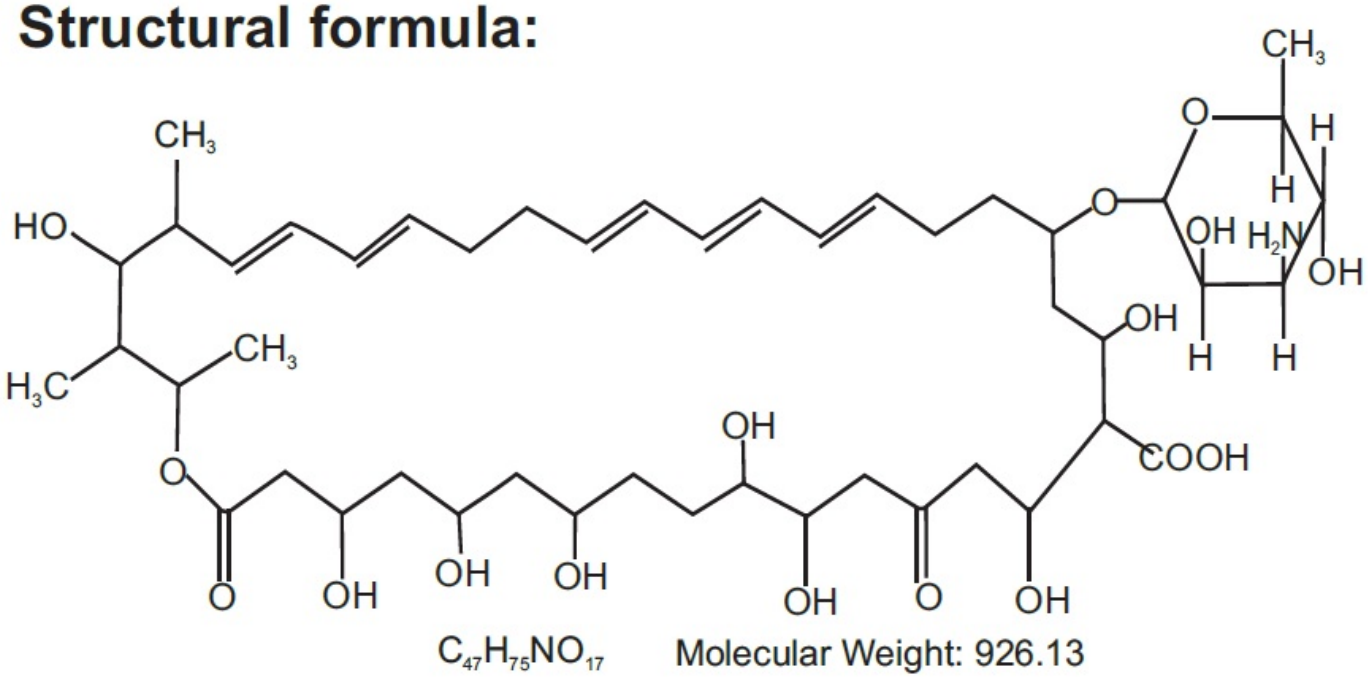
Rx only

FOR TOPICAL USE ONLY • NOT FOR OPHTHALMIC USE

DESCRIPTION

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

Structural formula:



Nystatin cream is for dermatologic use.
Nystatin cream for topical use, contains 100,000 USP Nystatin Units in an aqueous cream base containing aluminium hydroxide, ceteareth-15, polyethylene glycol monostearate, glycerol monostearate, propylene glycol, purified water, simethicone emulsion, non-crystallizing sorbitol solution, titanium dioxide, white petrolatum with methyl paraben and propyl paraben as preservatives.

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 & 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 PRECAUTIONS

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 PATIENTS

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.

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

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 & 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 yellow to light green cream. It is supplied as:
15 gram Tube NDC 33342-469-15
30 gram Tube NDC 33342-469-30

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Avoid freezing.

Manufactured for:
Macleods Pharma USA, Inc.

Princeton, NJ 08540

Manufacturer:
Macleods Pharmaceuticals Limited
At Oxalis Labs
Baddi, Himachal Pradesh, INDIA

Rev. 08/2021

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Nystatin Cream USP, 100000 units per gram
Pack Count: 15 gms Tube
NDC: 33342-469-15

Each gram contains: 100,000 USP Nystatin Units in an aqueous cream base containing aluminium hydroxide, ceteareth-15, polyethylene glycol monostearate, glycerol monostearate, propylene glycol, purified water, simethicone emulsion, non-crystallizing sorbitol solution, titanium dioxide, white petrolatum with methyl paraben and propyl paraben as preservatives

Usual Dosage: Apply liberally to affected areas twice daily. See prescribing information for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].
Avoid freezing

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube. Push cap until tube end is punctured. Screw cap back onto reseal tube.

Keep this and all medications out of the reach of children

MACLEODS
Manufactured for :
Macleods Pharma USA, Inc.
Princeton, NJ 08540

Manufacturer :
Macleods Pharmaceuticals Ltd.
At Oxalis Labs
Baddi, Himachal Pradesh, INDIA

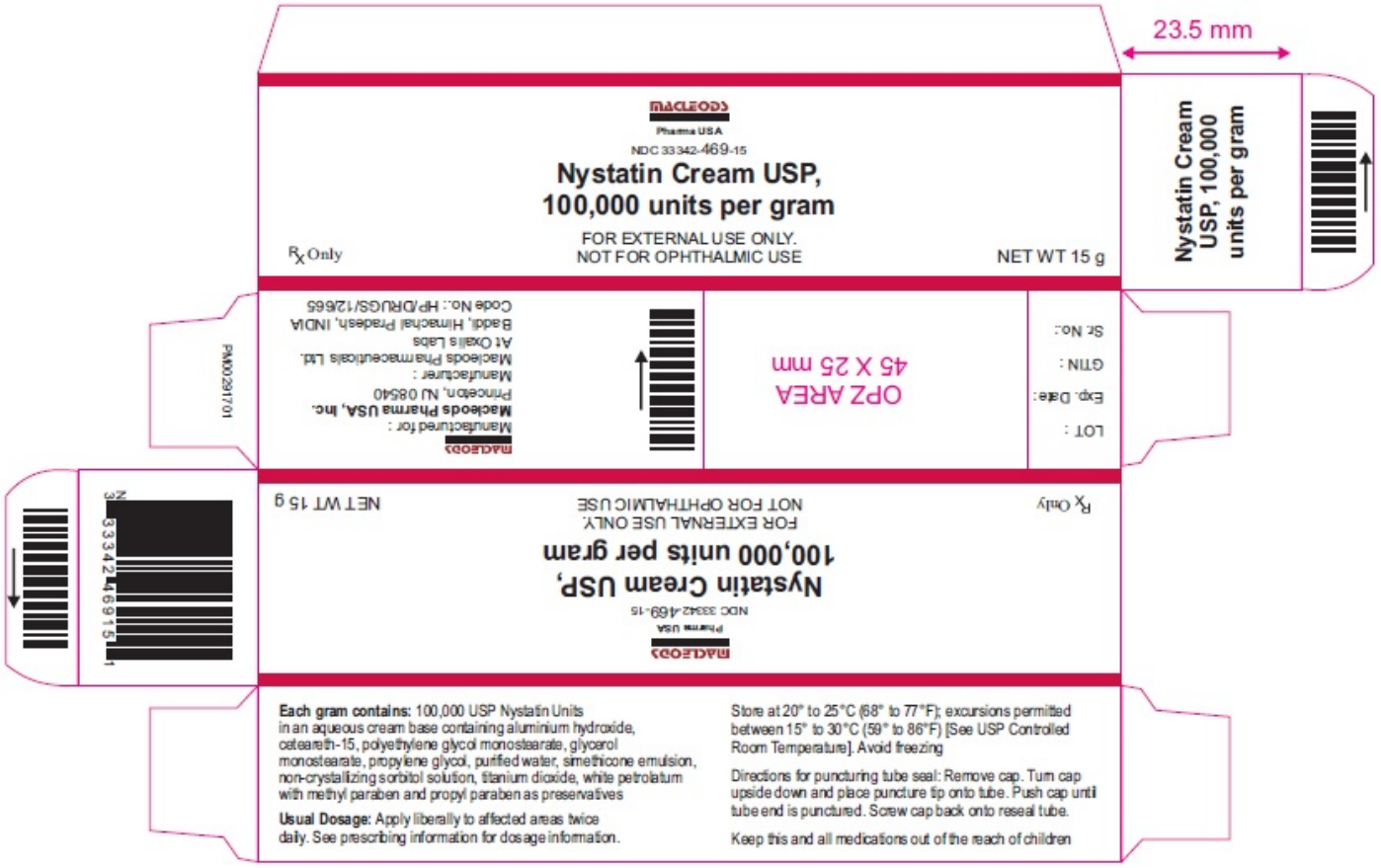
Code No.: HP/DRUGS/12/665

See LOT and EXP. Date

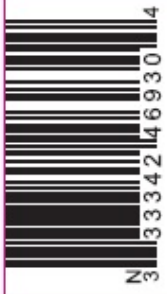
PM00291601

Nystatin Cream USP, 100000 units/gram

Pack Count: 15 gms carton
NDC: 33342-469-15



Nystatin Cream USP, 100000 units per gram
Pack Count: 30 gms Tube
NDC: 33342-469-30



MACLEODS
Pharma USA

NDC 33342-469-30

Nystatin Cream USP, 100,000 units per gram

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE

℞ Only

NET WT 30 g

Each gram contains: 100,000 USP Nystatin Units in an aqueous cream base containing aluminium hydroxide, ceteareth-15, polyethylene glycol monostearate, glycerol monostearate, propylene glycol, purified water, simethicone emulsion, non-crystallizing sorbitol solution, titanium dioxide, white petrolatum with methyl paraben and propyl paraben as preservatives

Usual Dosage: Apply liberally to affected areas twice daily. See prescribing information for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Avoid freezing

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube. Push cap until tube end is punctured. Screw cap back onto reseal tube.

Keep this and all medications out of the reach of children

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See LOT and EXP. Date ➧

PM00291901

Nystatin Cream USP, 100000 units/gram
Pack Count: 30 gms carton
NDC: 33342-469-30

NYSTATIN

nystatin cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:33342-469
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
PETROLATUM (UNII: 4T6H12BN9U)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CETEARETH-15 (UNII: 867H4YOZ8Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33342-469-15	1 in 1 CARTON	08/25/2021	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:33342-469-30	1 in 1 CARTON	08/25/2021	
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	ANDA213566	08/25/2021	

Labeler - Macleods Pharmaceuticals Limited (862128535)

Establishment

Name	Address	ID/FEI	Business Operations
OXALIS LABS		860120472	ANALYSIS(33342-469) , LABEL(33342-469) , MANUFACTURE(33342-469) , PACK(33342-469)

Revised: 8/2021 Macleods Pharmaceuticals Limited