

**NYSTATIN- nystatin cream**  
**Preferred Pharmaceuticals Inc.**

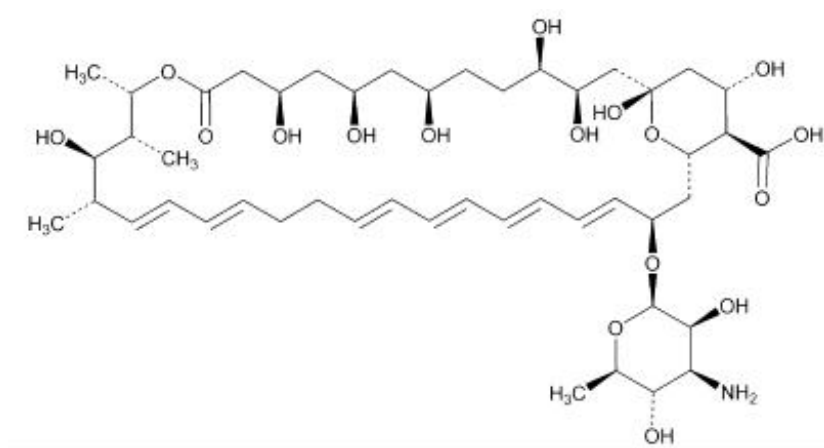
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**Nystatin Cream USP, 100,000 units per gram**

**FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE**

**DESCRIPTION**

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

Structural formula:



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<b>Molecular formula</b>	: C <sub>47</sub> H <sub>75</sub> NO <sub>17</sub>
<b>Molecular weight</b>	: 926.09 g/mol

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Nystatin cream is for dermatologic use.

Nystatin cream, USP for topical use, contains 100,000 USP nystatin units per gram.  
Inactive ingredients: aluminium hydroxide gel, cetareth-15, mono- and di- glyceride, polyoxyl 8 stearate, propylene glycol, simethicone emulsion, sorbitol solution, titanium dioxide, white petrolatum, methylparaben and propylparaben.

**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*, *Trichophyton 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. stellatoidea*) 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 their 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 PATIENTS

Patients using these medications should receive the following information and instructions:

1. The patient should be instructed to use these medications 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 its 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 health is complete.

**HOW SUPPLIED**

Nystatin Cream, USP, 100,000 units per gram is a yellow to light green color cream available as follows:

NDC 68788-8631-1 15 g tube

NDC 68788-8631-3 30g tube

**STORAGE AND HANDLING**

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



**Manufactured by:**

TORRENT PHARMACEUTICALS LTD., Pithampur-454775, INDIA .

**Manufactured for:**

TORRENT PHARMA INC., Basking Ridge, NJ 07920

8088981  
2022

August

Preferred Pharmaceuticals Inc.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

<p><b>Nystatin Cream USP 100,000 units per gram</b> Generic for Mycostatin Each gram contains: 100,000 units of nystatin in an aqueous cream base. <b>Pkg Size:</b> Exp Date: Lot#: Ins: Batch#: Ins: Mfg: Torrent Pharmaceuticals Limited Prod#: Ins: <b>Warning</b> Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° and 30°C (59° and 86°F) See USP Controlled Room Temperature. Avoid freezing. Rx Only. Keep out of the reach of children. For external use only. Not for ophthalmic use.</p>	<p><b>PREFERRED</b> Pharmaceuticals, Inc.      Anaheim, Ca 92807</p>	<p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Nystatin Cream USP 100,000 units per gram Qty: Ins: Lot#: Bat#:  Prod# (NDC):  Nystatin Cream USP 100,000 units per gram Qty: Ins: Lot#: Bat#: Prod# (NDC):  Nystatin Cream USP 100,000 units per gram Qty: Ins: Lot#: Bat#: Prod# (NDC):  Nystatin Cream USP 100,000 units per gram Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log Chart Billing Patient</p>
<p>Directions English Apply externally _____ times a day.</p>		<p>Instrucciones Espanol: Aplique externamente _____ veces al dia.</p>		

# NYSTATIN

nystatin cream

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68788-8631(NDC:13668-595)
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)	NYSTATIN	100000 U in 1 g

## Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CETEARETH-15 (UNII: 867H4YOZ8Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	yellow (Yellow to light green)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8631-1	15 g in 1 TUBE; Type 0: Not a Combination Product	04/15/2024	
2	NDC:68788-8631-3	30 g in 1 TUBE; Type 0: Not a Combination Product	04/15/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA212557	04/15/2024	
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**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

**Establishment**

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8631)

Revised: 4/2024

Preferred Pharmaceuticals Inc.