NYSTATIN CREAM- nystatin cream cream
Crown Laboratories

Nystatin Cream USP

Rx Only

Nystatin Cream, USP

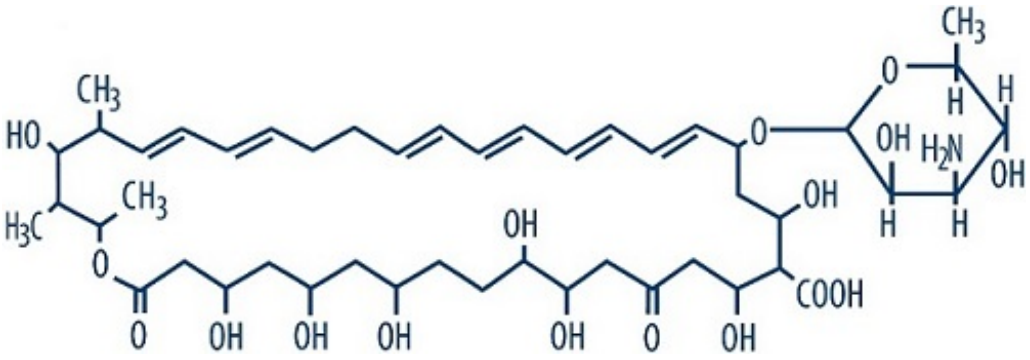
For external use only.

Not for ophthalmic use. Rx Only

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.

Each gram contains 100,000 USP Nystatin Units in an aqueous, cream base consisting of purified water, emulsifying wax, mineral oil, propylene glycol, sorbitol solution, cetyl palmitate, sorbic acid and potassium sorbate.

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**.)

To report SUSPECTED ADVERSE REACTIONS, contact Crown Laboratories, Inc. at 1-423-926-4413 or FDA at 1-800-FDA-1088 or https://www.fda.gov/Safety/MedWatch/

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 light yellow to yellow cream that is supplied in:
15 gram tube NDC 0316-0221-15
30 gram tube NDC 0316-0221-30

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

Manufactured and Distributed by:
Crown Laboratories, Inc., Johnson City, TN 37604

Printed in USA

P9526.00

15 gram tube

NDC 0316-0221-15

Rx Only

Nystatin Cream, USP

100,000 units per gram

WARNING: Keep out of reach of children.

For external use only.

Not for ophthalmic use.

15 grams

Each gram contains: 100,000 USP Nystatin Units in an aqueous, cream base consisting of purified water, emulsifying wax, mineral oil, propylene glycol, sorbitol solution, cetyl palmitate, sorbic acid and potassium sorbate.

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

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

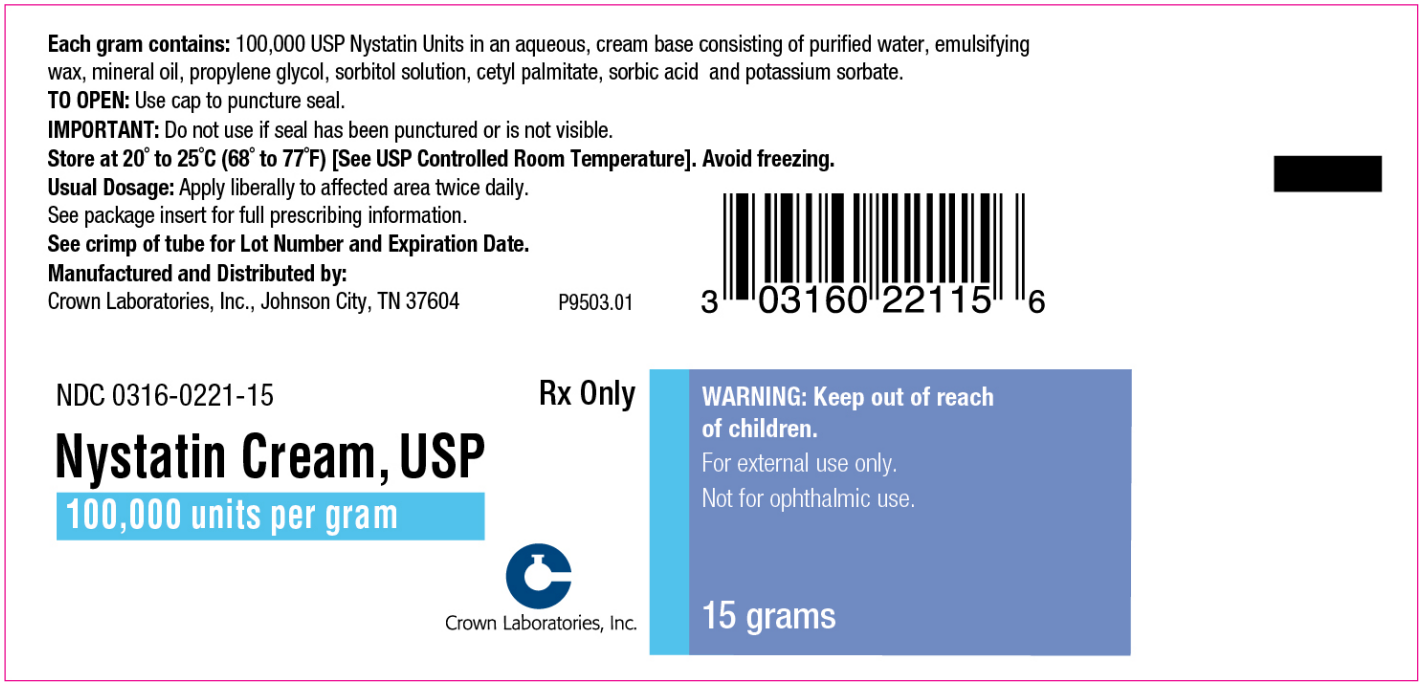
Usual Dosage: Apply liberally to affected area twice daily. See package insert for full prescribing information.

See crimp of tube for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc., Johnson City, TN 37604

P9503.01



15 gram carton

NDC 0316-0221-15

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15 grams

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

IMPORTANT: Do not use if seal has been punctured or is not visible.

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

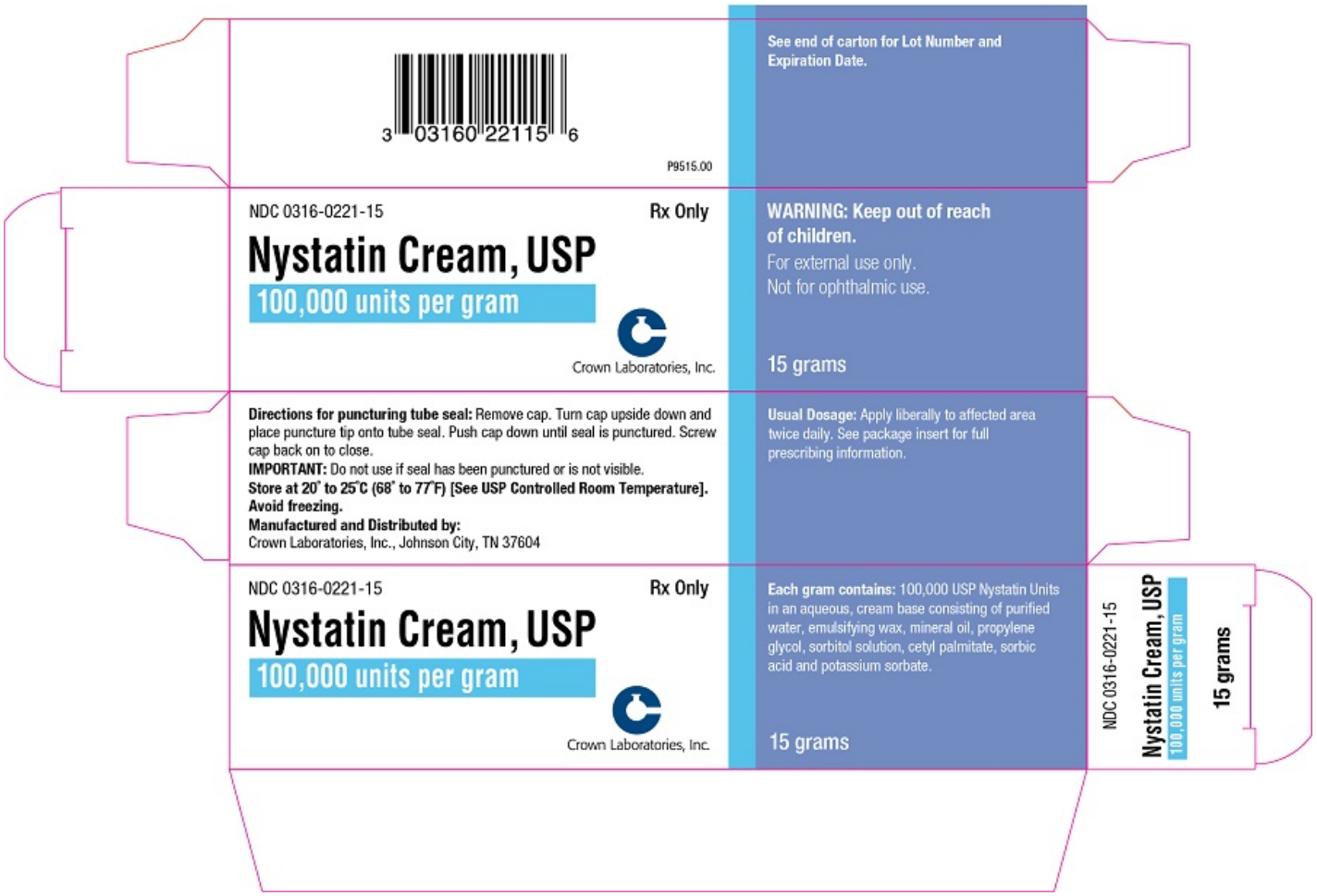
Usual Dosage: Apply liberally to affected area twice daily. See package insert for full prescribing information.

See end of carton for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc., Johnson City, TN 37604

P9515.00



NYSTATIN CREAM

nystatin cream cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0316-0221
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**
MINERAL OIL (UNII: T5L8T28FGP)	
SORBIC ACID (UNII: X045WJ989B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

SORBITOL (UNII: 506T60A25R)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0221-15	1 in 1 CARTON	10/10/2017	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0316-0221-30	1 in 1 CARTON	10/10/2017	
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	ANDA207733	10/10/2017	

Labeler - Crown Laboratories (079035945)

Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-0221)

Revised: 10/2023 Crown Laboratories