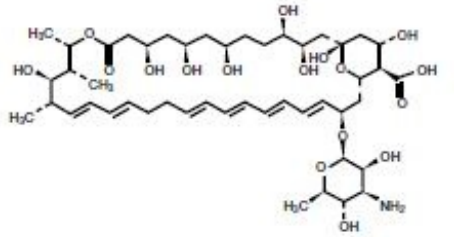
NYSTATIN- nystatin ointment
Leading Pharma, LLC

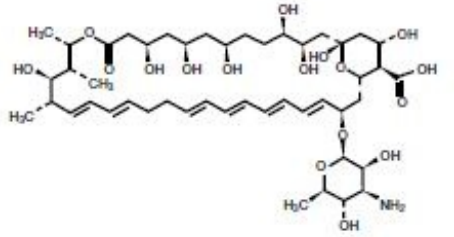
Nystatin Ointment, USP
Rx Only
For Topical Use Only • Not for Ophthalmic Use

DESCRIPTION

Nystatin is a polyene antifungal antibiotic drug obtained from Streptomyces nursei.
Structural formula:



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



Nystatin Ointment is for dermatologic use. Nystatin Ointment for topical use contains 100,000 USP nystatin units per gram in a polyethylene and mineral oil base.

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

Nystatin Ointment is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nystatin Ointment is contraindicated in patients with a history of hypersensitivity to any of their components.

PRECAUTIONS

General

Nystatin Ointment 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 these medications as directed (including the replacement of missed doses). These medications are not for any disorder other than that for which they are 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 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 topical preparation. It also is not known whether these preparations can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin topical preparations 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**).

ADVERSE REACTIONS

The frequency of adverse events reported in patients using Nystatin Ointment preparations 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**).

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS.
YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088 OR LEADING PHARMA, LLC AT 1-844-740-7500.

DOSAGE AND ADMINISTRATION

Nystatin Ointment

Adults and Pediatric Patients (Neonates and Older)

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

HOW SUPPLIED

Nystatin Ointment, USP (100,000 nystatin units per gram) is a yellow ointment available as follows:

NDC 69315-307-15 **15 gram tube**

NDC 69315-307-30 **30 gram tube**

STORAGE

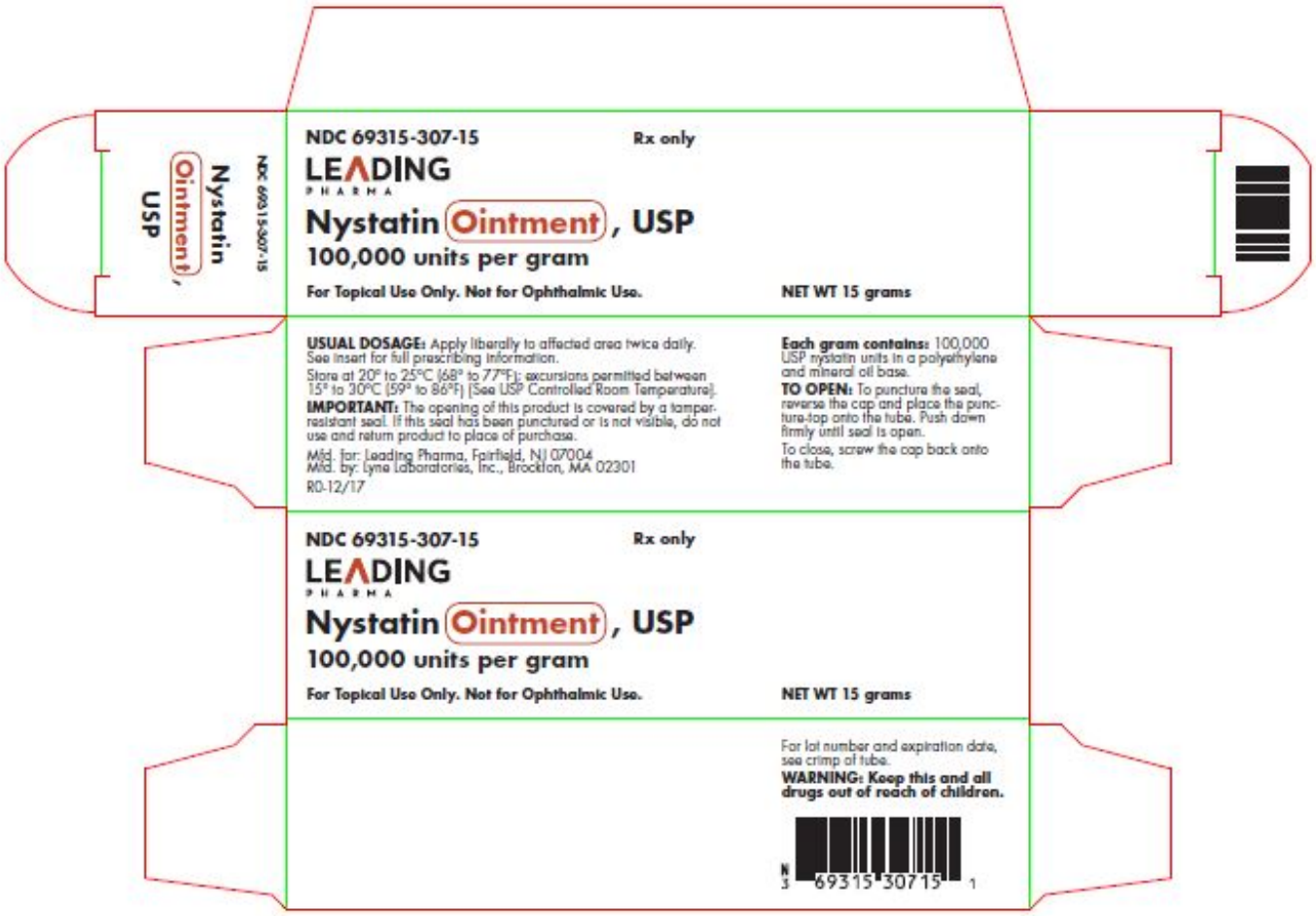
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured for: Leading Pharma LLC, Fairfield, NJ 07004

Manufactured by: Lyne Laboratories, Inc. Brockton, MA 02301

R0-12/17

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL


NDC 69315-307-15
Rx only
LEADING
PHARMA
Nystatin Ointment, USP
100,000 units per gram
For Topical Use Only. Not for Ophthalmic Use.
NET WT 15 grams
USUAL DOSAGE: Apply liberally to affected area twice daily. See insert for full prescribing 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].
IMPORTANT: The opening of this product is covered by a tamper-resistant seal. If this seal has been punctured or is not visible, do not use and return product to place of purchase.
Mfd. for: Leading Pharma, Fairfield, NJ 07004
Mfd. by: Lyne Laboratories, Inc., Brockton, MA 02301
R0-12/17
Each gram contains: 100,000 USP nystatin units in a polyethylene and mineral oil base.
TO OPEN: To puncture the seal, reverse the cap and place the puncture-top onto the tube. Push down firmly until seal is open.
To close, screw the cap back onto the tube.
For lot number and expiration date, see crimp of tube.
WARNING: Keep this and all drugs out of reach of children.
N 3 69315 30715 1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Nystatin Ointment, USP
100,000 units per gram
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NET WT 15 grams
Each gram contains: 100,000 USP nystatin units in a polyethylene and mineral oil base.
USUAL DOSAGE: Apply liberally to affected area twice daily. See insert for full prescribing information.
WARNING: Keep this and all drugs out of reach of children.
TO OPEN: Use cap to puncture seal.
IMPORTANT: Do not use if seal has been punctured or is not visible.
For lot number and expiration date, see crimp of tube.
Mfd. for: Leading Pharma, Fairfield, NJ 07004
Mfd. by: Lyne Laboratories, Inc., Brockton, MA 02301
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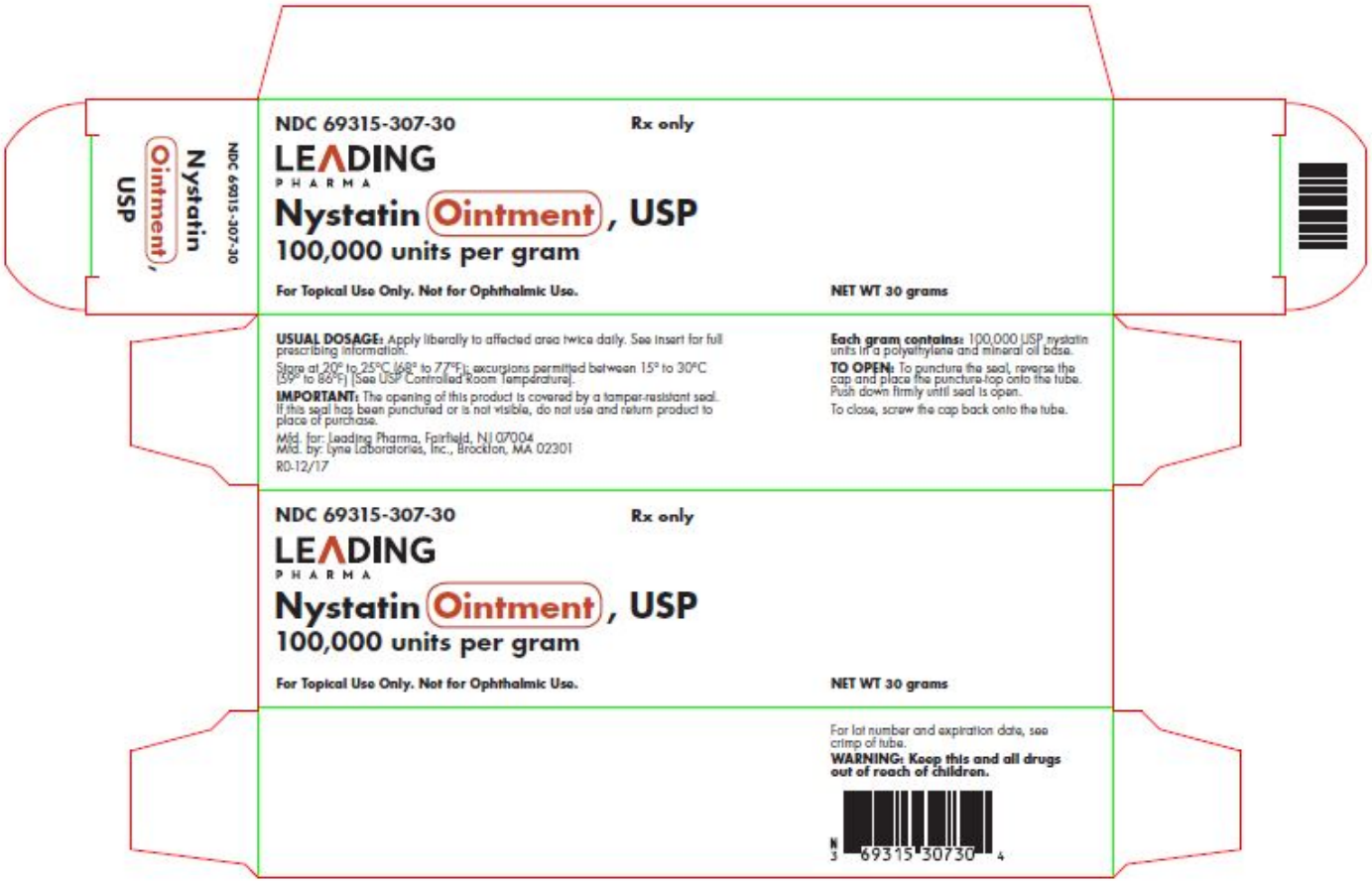

NYSTATIN

nystatin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69315-307
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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69315-307-15	1 in 1 CARTON	08/19/2019	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69315-307-30	1 in 1 CARTON	08/19/2019	
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	ANDA209082	08/19/2019	

Labeler - Leading Pharma, LLC (079575060)

Registrant - Lyne Laboratories, Inc (053510459)

Establishment

Name	Address	ID/FEI	Business Operations
Lyne Laboratories, Inc		053510459	manufacture(69315-307)

Revised: 9/2019 Leading Pharma, LLC