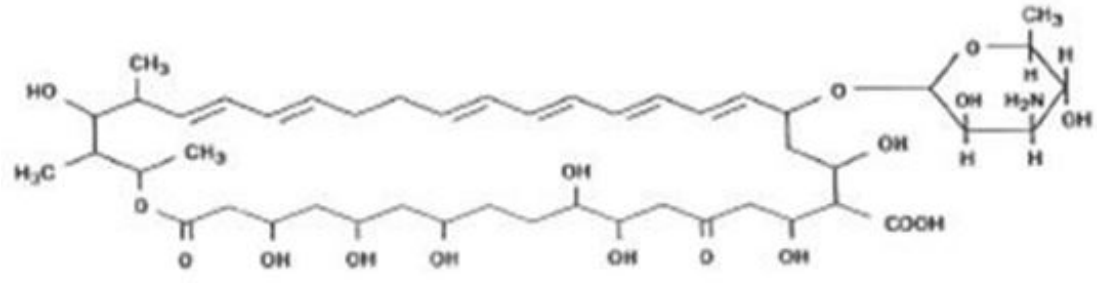
NYSTATIN- nystatin powder
Leading Pharma, LLC

NYSTATIN TOPICAL POWDER
Rx Only
FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE

DESCRIPTION

Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces noursei*. The molecular formula for Nystatin is C47H75NO17. The molecular weight of Nystatin is 926.1.
Structural formula:



Nystatin topical powder is for dermatologic use.
Nystatin topical powder contains 100,000 nystatin units per gram dispersed in talc.

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 topical powder is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nystatin topical powder is contraindicated in patients with a history of hypersensitivity to **any** of its components.

PRECAUTIONS

General

Nystatin topical powder 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

HOW SUPPLIED

Nystatin topical powder is supplied as 100,000 units nystatin per gram in plastic squeeze bottles:

15g (NDC 69315-306-15)

30g (NDC 69315-306-30)

60g (NDC 69315-306-60)

STORAGE

Store at 20°C to 25°C (68°F to 77°F)[see USP Controlled Room Temperature]; avoid excessive heat (40°C/104°F).

Keep tightly closed.

Manufactured for:

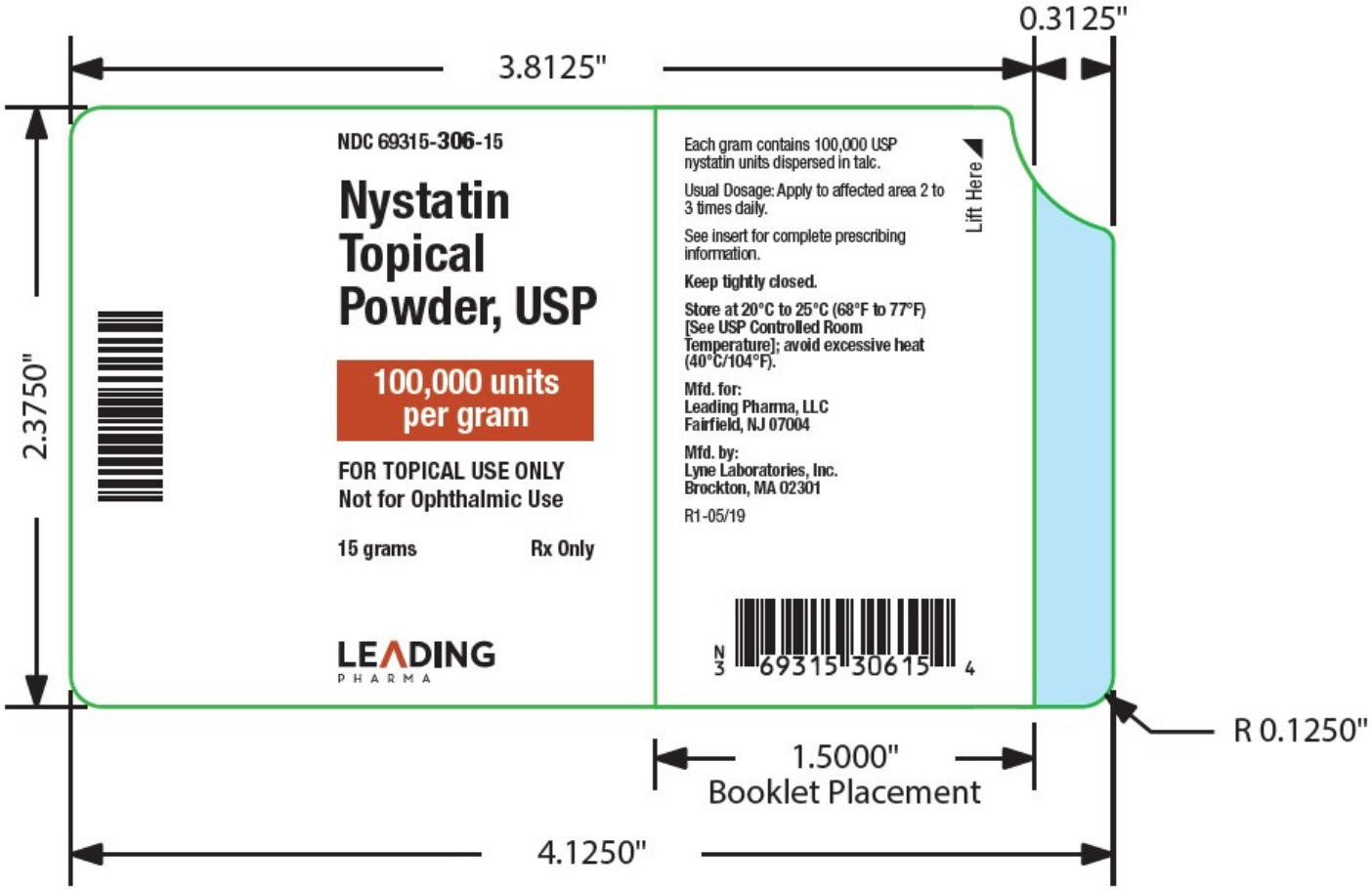
Leading Pharma LLC, Fairfield, NJ 07004

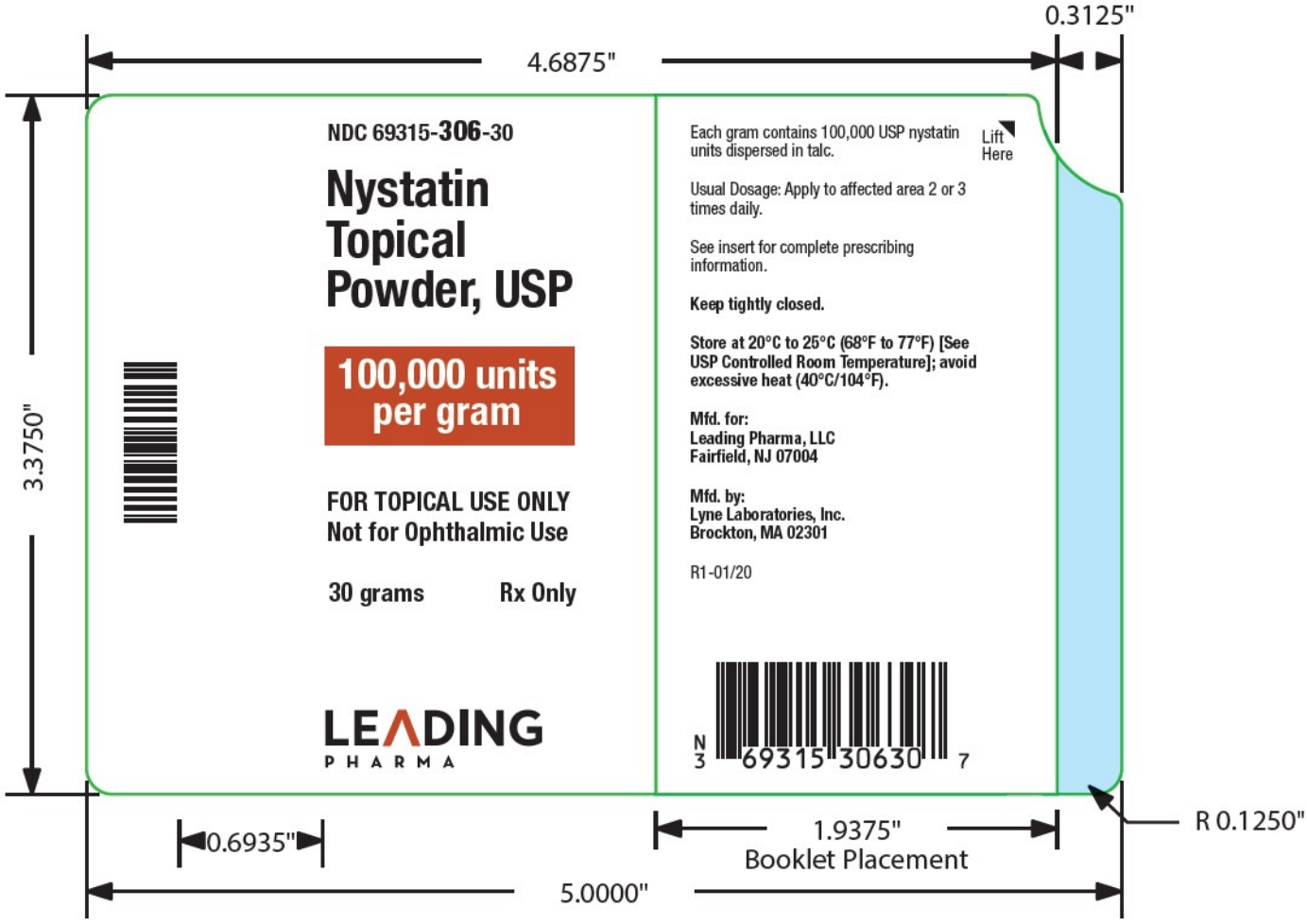
Manufactured by:

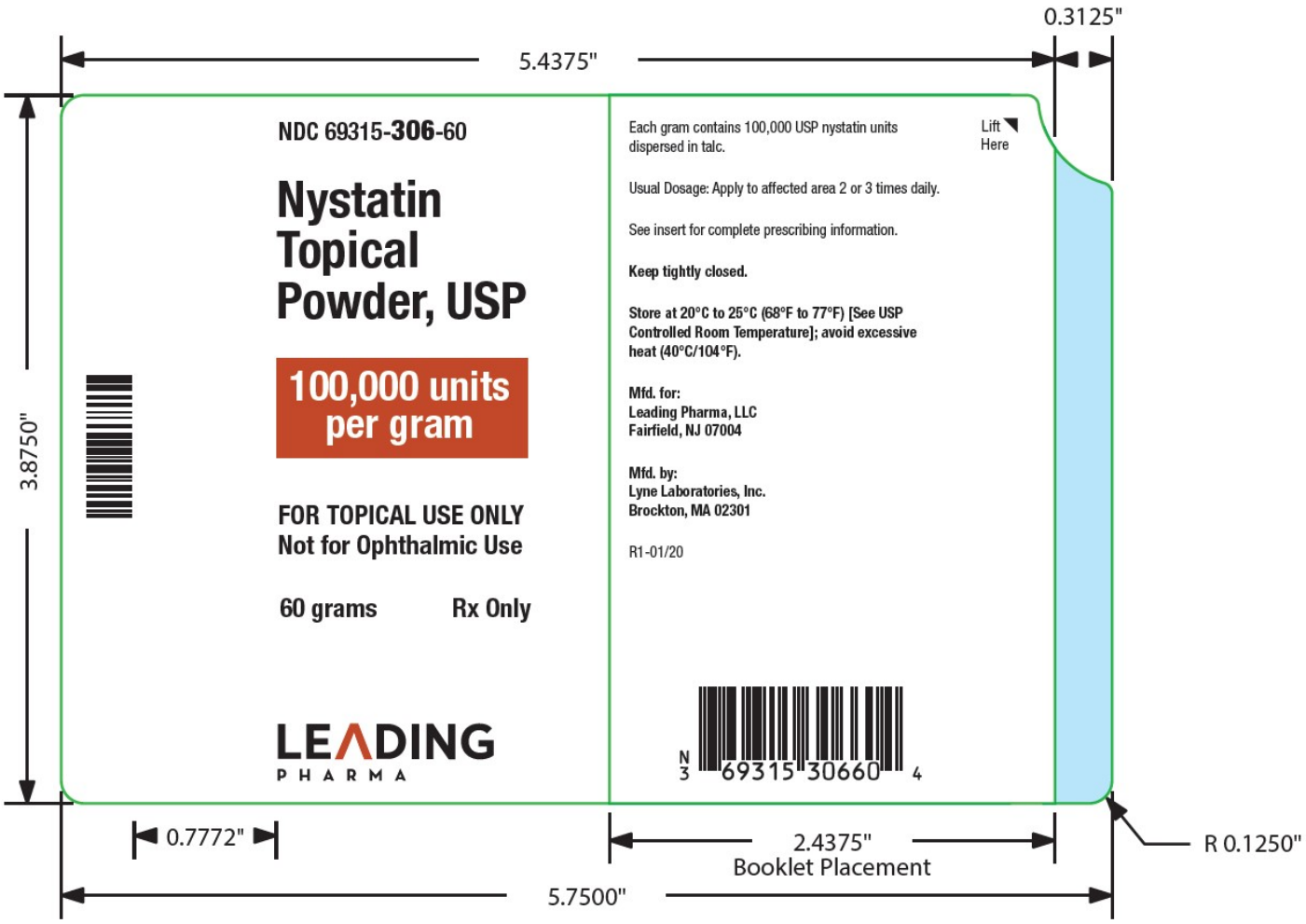
Lyne Laboratories, Inc. Brockton, MA 02301

R1-01/20

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL




0.3125"
4.6875"
3.3750"
NDC 69315-306-30
Nystatin Topical Powder, USP
100,000 units per gram
FOR TOPICAL USE ONLY
Not for Ophthalmic Use
30 grams
Rx Only
LEADING PHARMA
Each gram contains 100,000 USP nystatin units dispersed in talc.
Lift Here
Usual Dosage: Apply to affected area 2 or 3 times daily.
See insert for complete prescribing information.
Keep tightly closed.
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]; avoid excessive heat (40°C/104°F).
Mfd. for:
Leading Pharma, LLC
Fairfield, NJ 07004
Mfd. by:
Lyne Laboratories, Inc.
Brockton, MA 02301
R1-01/20
N 3 69315 30630 7
R 0.1250"
0.6935"
1.9375"
Booklet Placement
5.0000"



NYSTATIN

nystatin powder

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69315-306
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**
TALC (UNII: 7SEV7J4R1U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:69315-306-15	15 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2018	
2	NDC:69315-306-30	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2018	
3	NDC:69315-306-60	60 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/23/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208838	04/23/2018	

Labeler - Leading Pharma, LLC (079575060)

Registrant - Lyne Laboratories, Inc (053510459)

Establishment

Name	Address	ID/FEI	Business Operations
Lyne Laboratories, Inc		053510459	manufacture(69315-306)

Revised: 4/2024 Leading Pharma, LLC