

NYSTATIN- nystatin powder

RedPharm Drug

NYSTATIN TOPICAL POWDER

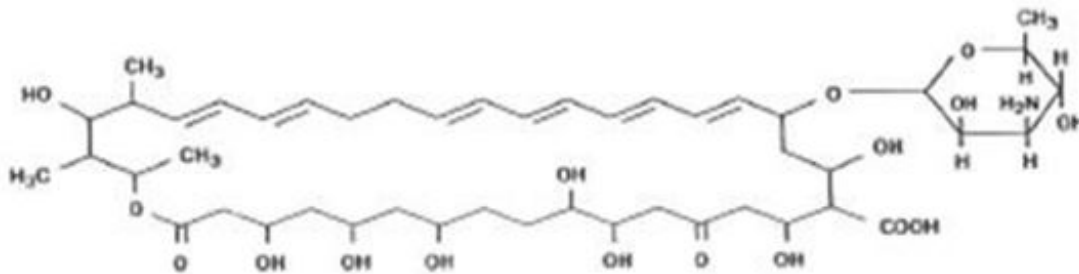
Rx Only

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.

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 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.

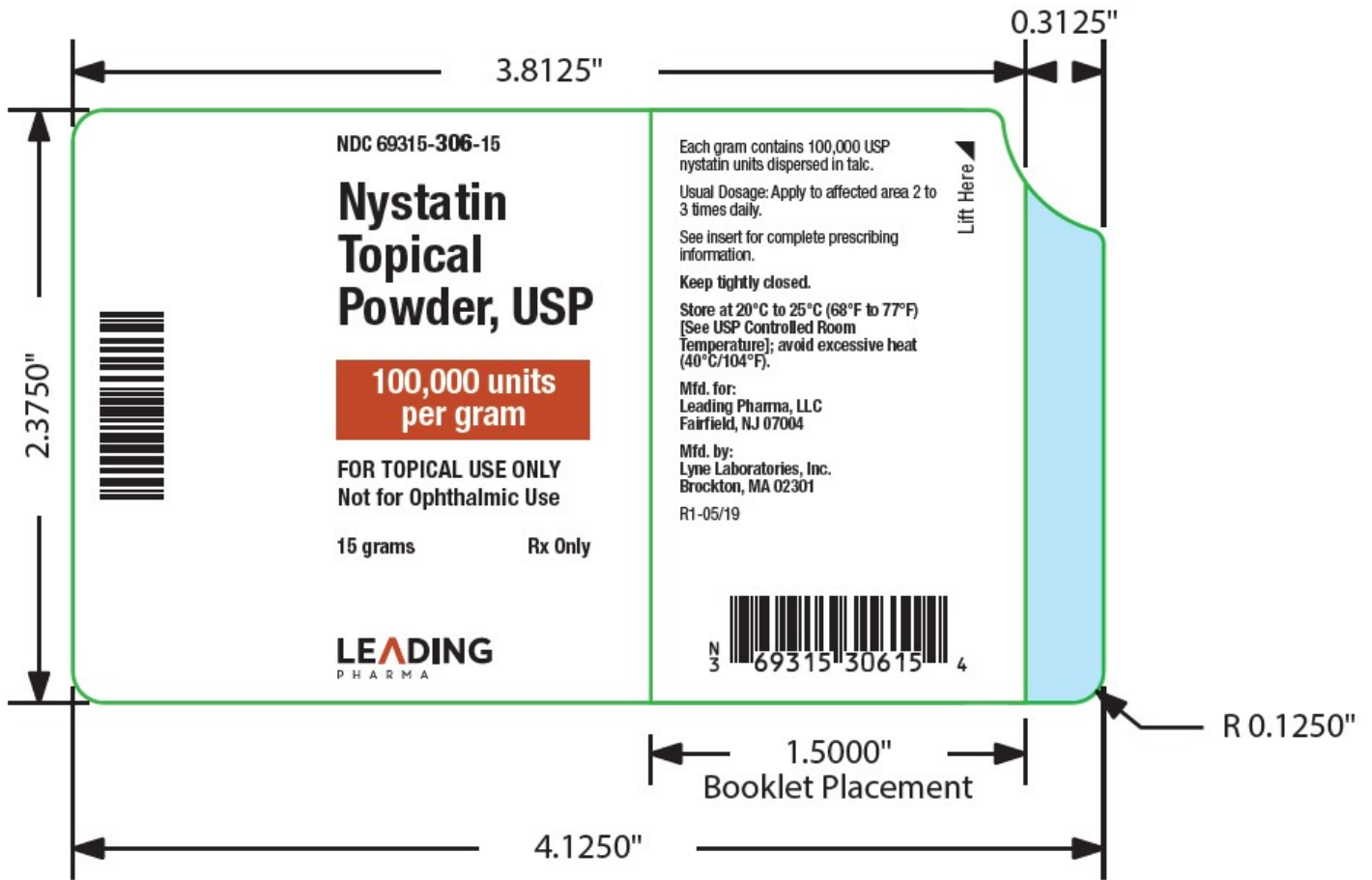
Manufactured for:

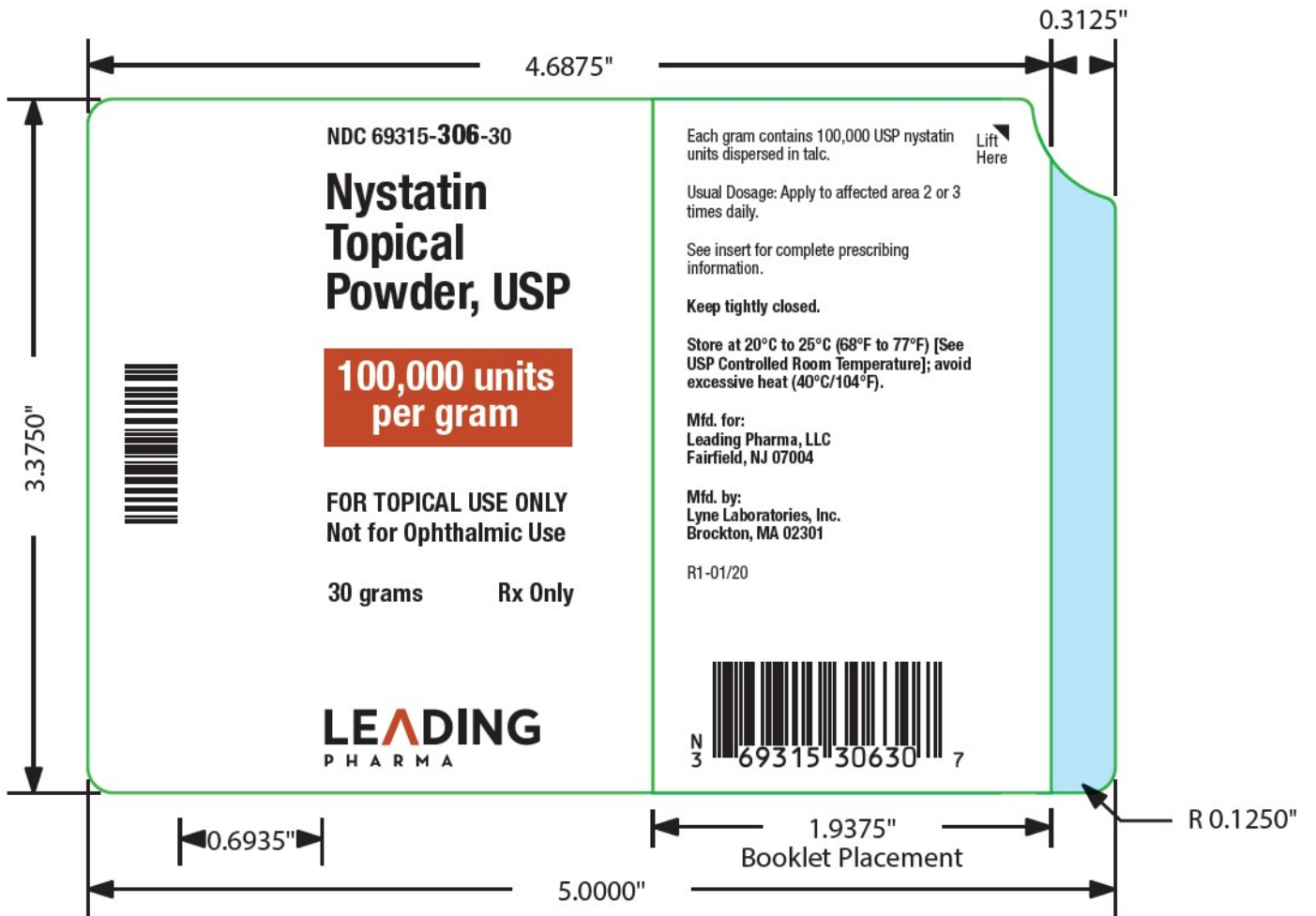
Leading Pharma LLC, Fairfield, NJ 07004

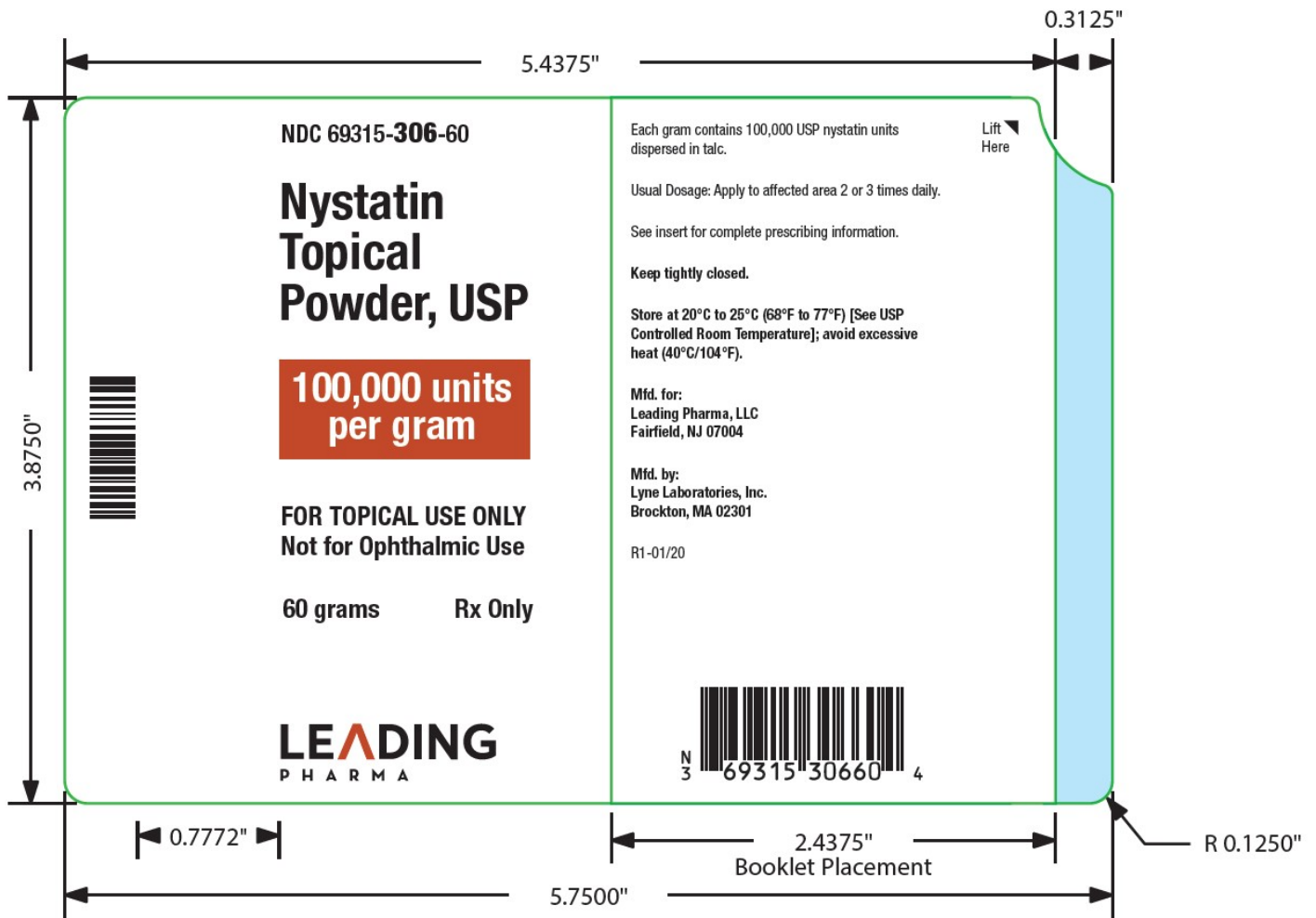
Manufactured by:

Lyne Laboratories, Inc. Brockton, MA 02301

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL







NYSTATIN
nystatin powder

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67296-1501(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

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1501-3	30 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 - RedPharm Drug (828374897)

Registrant - RedPharm Drug (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
Lyne Laboratories, Inc		828374897	repack(67296-1501)

Revised: 8/2024

RedPharm Drug