

NYSTATIN - nystatin powder
Zydus Lifesciences Limited

Nystatin Topical Powder, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1585-1

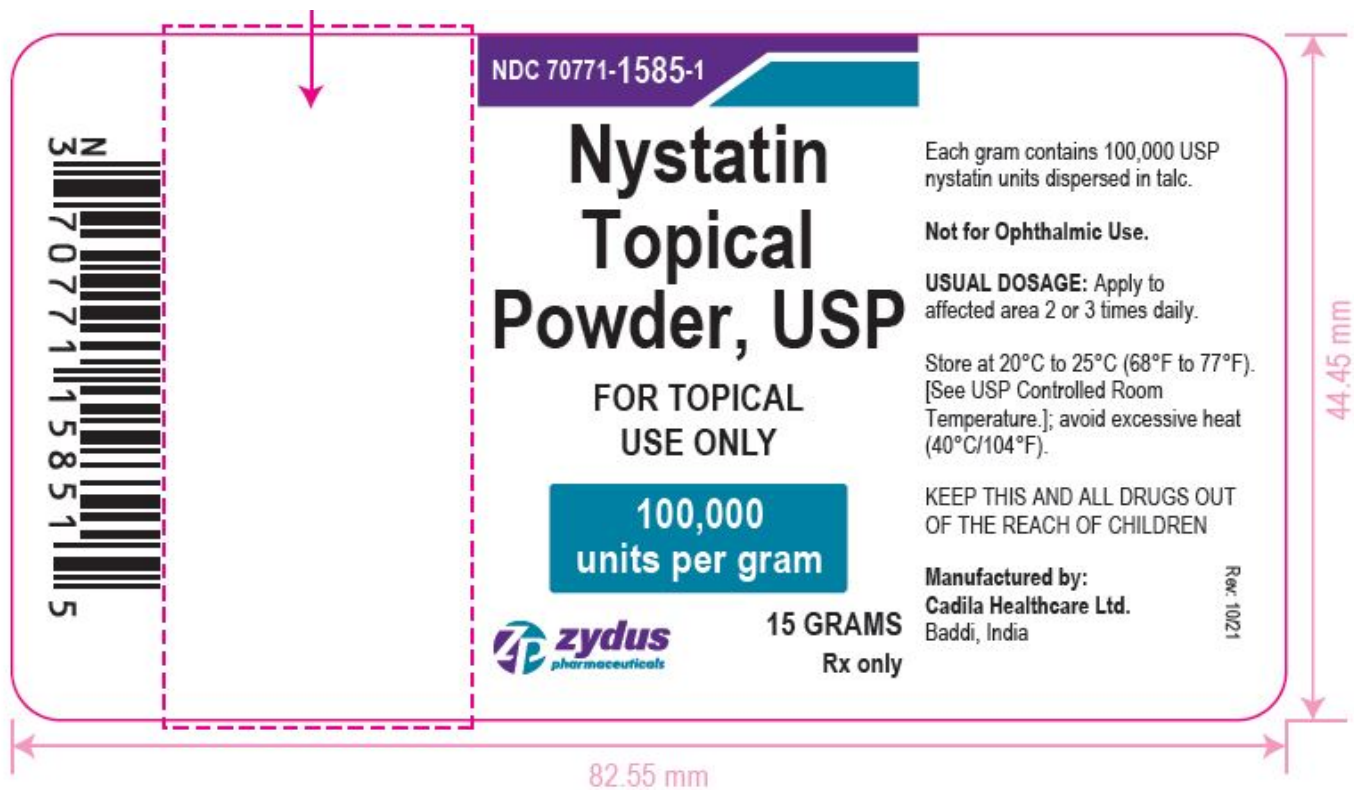
Nystatin Topical Powder, USP

FOR TOPICAL USE ONLY

100,000 units per gram

Rx Only

15 GRAMS



NDC 70771-1585-2

Nystatin Topical Powder, USP

FOR TOPICAL USE ONLY

100,000 units per gram

Rx Only

30 GRAMS

NDC 70771-1585-2

**Nystatin
Topical
Powder, USP**

FOR TOPICAL
USE ONLY

100,000
units per gram

zydus
pharmaceuticals

30 GRAMS
Rx only

Each gram contains 100,000 USP nystatin units dispersed in talc.

Not for Ophthalmic Use.

USUAL DOSAGE: Apply to affected area 2 or 3 times daily.

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 THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Manufactured by:
Cadila Healthcare Ltd.
Baddi, India

Rev. 10/21

101.6 mm

50.8 mm

NDC 70771-1585-3

Nystatin Topical Powder, USP

FOR TOPICAL USE ONLY

100,000 units per gram

Rx Only

60 GRAMS

NDC 70771-1585-3

Nystatin Topical Powder, USP

Each gram contains 100,000 USP nystatin units dispersed in talc.

Not for Ophthalmic Use.

USUAL DOSAGE: Apply to affected area 2 or 3 times daily.

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


FOR TOPICAL USE ONLY

100,000 units per gram

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Manufactured by:
Cadila Healthcare Ltd.
Baddi, India

Rev: 10/21

 **zydus**
pharmaceuticals

60 GRAMS
Rx only

3 N
70771115853
9

123.825 mm

88.9 mm

NYSTATIN

nystatin powder

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1585
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:70771-1585-1	15 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2021	
2	NDC:70771-1585-3	60 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2021	
3	NDC:70771-1585-2	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208581	10/06/2021	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		677605858	ANALYSIS(70771-1585) , MANUFACTURE(70771-1585)

Revised: 10/2022

Zydus Lifesciences Limited