

NYSTATIN - nystatin ointment
Zydus Lifesciences Limited

Nystatin Ointment USP
For Topical Use Only
Not for Ophthalmic Use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1357-1

Nystatin Ointment USP, 15 g

Rx only

NDC 70771-1357-1

Nystatin Ointment, USP
100,000 units Per Gram
For Topical Use Only. Not for Ophthalmic Use.
WARNING: Keep this and all drugs out of the reach of children.

zydus
pharmaceuticals

15 g
Rx only

Each gram contains: 100,000 USP Nystatin units in an ointment base of light mineral oil and white petrolatum.
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) [see USP Controlled Room Temperature]
TO OPEN: Use cap to puncture the seal.
Important: Do not use if this seal has been punctured or is not visible.
 See crimp of tube for lot number and expiry date.

Manufactured by:
 Cadila Healthcare Ltd.
 Changodar, Ahmedabad, India

GUJDRUGS/28/1357
 Rev.: 06/18

3 70771 113571 4

NYSTATIN
 nystatin ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1357
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)	NYSTATIN	100000 U in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	YELLOW (YELLOW)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1357-1	15 g in 1 TUBE; Type 0: Not a Combination Product	08/08/2018	
2	NDC:70771-1357-2	30 g in 1 TUBE; Type 0: Not a Combination Product	08/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207767	08/08/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1357) , MANUFACTURE(70771-1357)

Revised: 11/2022

Zydus Lifesciences Limited