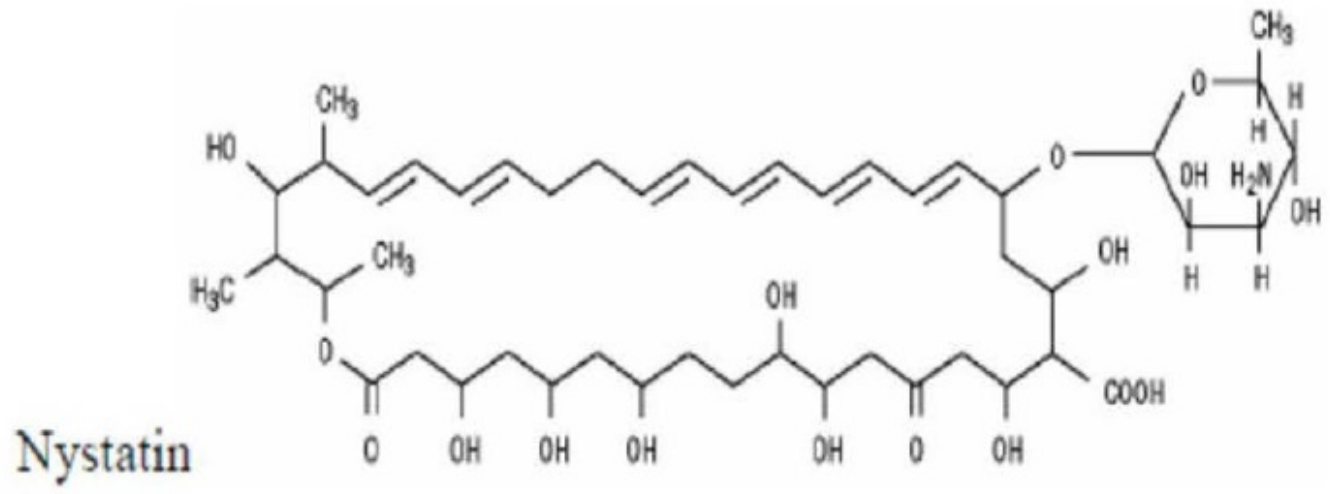
NYSTATIN- nystatin ointment
Zydus Pharmaceuticals (USA) Inc.

Nystatin Ointment, USP

DESCRIPTION

Nystatin is a polyene antifungal antibiotic drug obtained from *Streptomyces nursei.*

Structural formula:



Nystatin Ointment is for dermatologic use. Nystatin Ointment USP, for topical use only, contains 100,000 USP Nystatin Units per gram, in a white petrolatum and light mineral oil base.

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, 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 concentrations 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 Ointment 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 PATIENTS

Patients using these medications 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 a 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.**)

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 (100,000 USP Nystatin Units per gram) is a yellow colored ointment is supplied in 15g and 30g tubes.

NDC 68382-333-01 in tube of 15 gm

NDC 68382-333-02 in tube of 30 gm

STORAGE

NYSTATIN Ointment: Store at room temperature.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by:

Cadila Healthcare Limited

Changodar, Ahmedabad, India.

Distributed by:

Zydus Pharmaceuticals (USA) Inc.

Pennington, NJ 08534

Rev.: 06/18

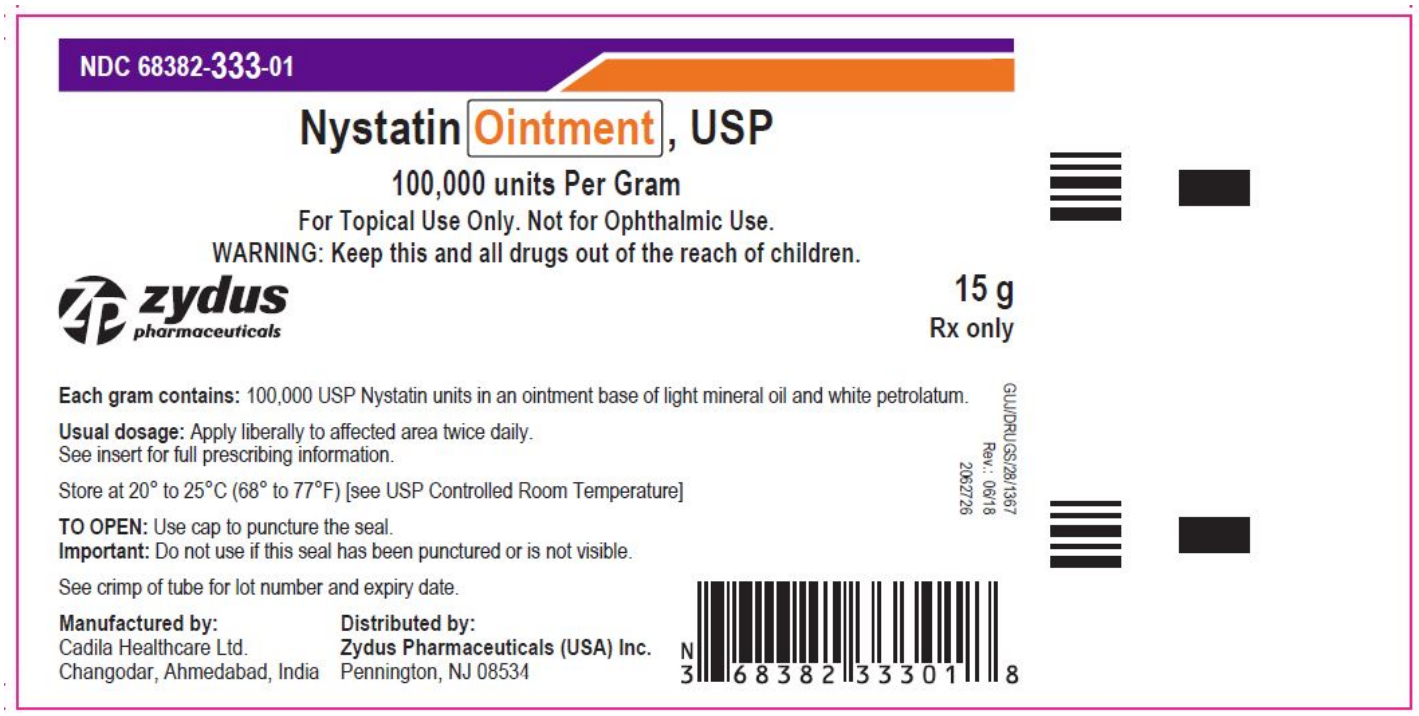
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

68382-333-01

Nystatin Ointment USP, 15 g

Rx only

Zydus



NYSTATIN

nystatin ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68382-333
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:68382-333-01	15 g in 1 TUBE; Type 0: Not a Combination Product	08/08/2018	
2	NDC:68382-333-02	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 Pharmaceuticals (USA) Inc. (156861945)

Registrant - Zydus Pharmaceuticals (USA) Inc. (156861945)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		650650802	ANALYSIS(68382-333) , MANUFACTURE(68382-333)

Revised: 12/2019 Zydus Pharmaceuticals (USA) Inc.