

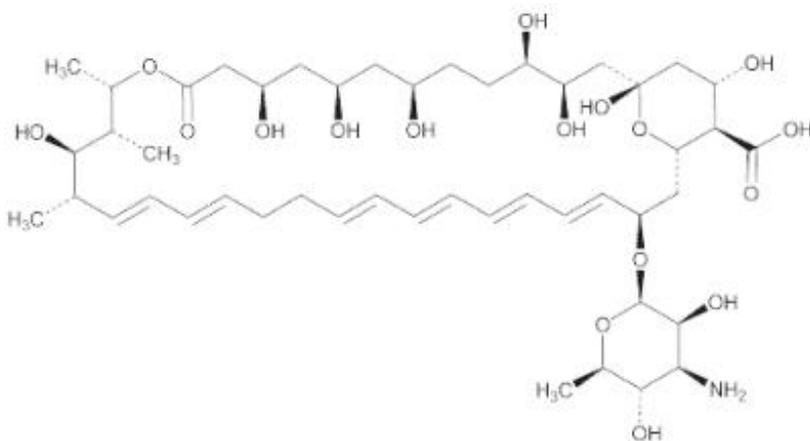
NYSTATIN- nystatin ointment
Torrent Pharmaceuticals Limited

NYSTATIN OINTMENT, USP
For Topical Use Only. Not for Ophthalmic Use.

DESCRIPTION

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

Structural formula:



Molecular formula	: C ₄₇ H ₇₅ NO ₁₇
Molecular weight	: 926.09 g/mol

Nystatin ointment is for dermatologic use. Nystatin ointment for topical use contains 100,000 USP nystatin units per gram in an ointment base of light mineral oil and white petrolatum.

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. 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 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 USP, 100,000 units per gram is a pale yellow to yellow color ointment available as follows:

NDC 13668-534-01 15 gram tube

NDC 13668-534-02 30 gram tube

STORAGE

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].



Manufactured by:

TORRENT PHARMACEUTICALS LTD., Pithampur-454775, INDIA .

Manufactured for:

TORRENT PHARMA INC., Basking Ridge, NJ 07920

8063926
2018

Revised June

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

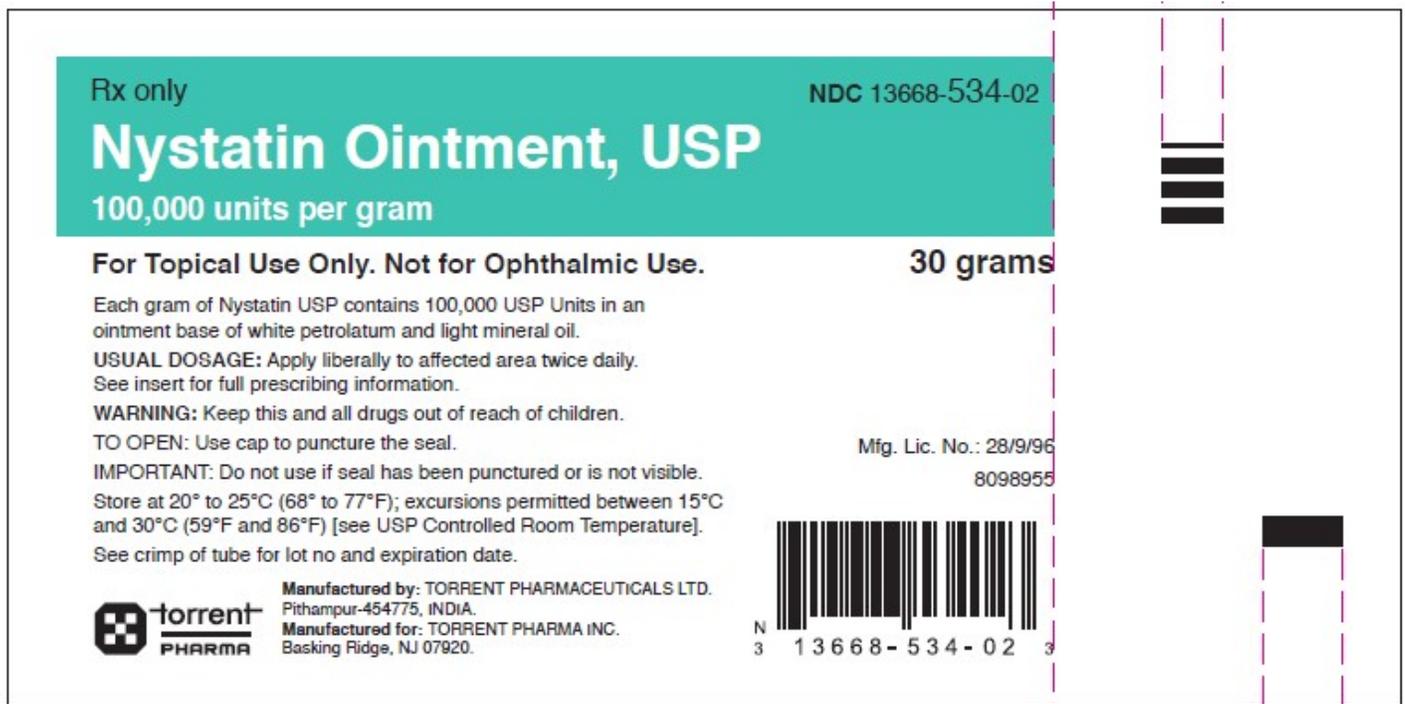
Nystatin Ointment, USP 15 grams (Tube label)

The image shows the principal display panel for a tube of Nystatin Ointment, USP 15 grams. The panel is rectangular with a teal header section. In the header, "Rx only" is on the left and "NDC 13668-534-01" is on the right. The product name "Nystatin Ointment, USP" is prominently displayed in white on the teal background, with "100,000 units per gram" below it. Below the header, the text "For Topical Use Only. Not for Ophthalmic Use." is on the left, and "15 grams" is on the right. The main body of the label contains detailed information: "Each gram of Nystatin USP contains 100,000 USP Units in an ointment base of white petrolatum and light mineral oil.", "USUAL DOSAGE: Apply liberally to affected area twice daily. See insert for full prescribing information.", "WARNING: Keep this and all drugs out of reach of children.", "TO OPEN: Use cap to puncture the seal.", "IMPORTANT: Do not use if seal has been punctured or is not visible.", "Store at 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. See crimp of tube for lot no and expiration date." On the right side of the label, "Mfg. Lic. No.: 28/9/96" and "8098954" are listed. At the bottom left is the Torrent Pharma logo and manufacturing information: "Manufactured by: TORRENT PHARMACEUTICALS LTD. Pithampur-454775, INDIA. Manufactured for: TORRENT PHARMA INC. Basking Ridge, NJ 07920." At the bottom center is a barcode with the number "3 13668-534-01 6" below it. On the right side of the label, there are three horizontal black bars and a small black rectangular area, both within dashed lines indicating fold or cut lines.

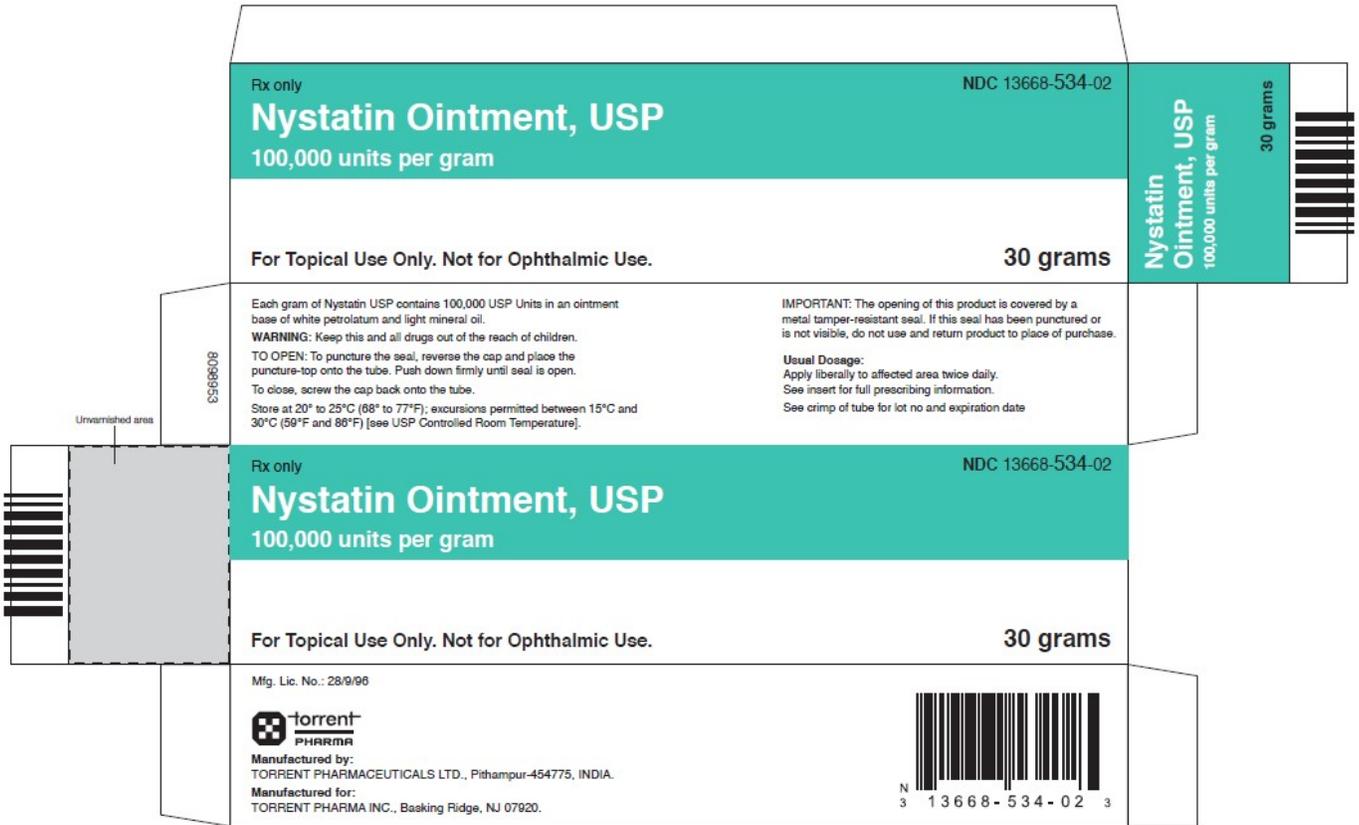
Nystatin Ointment, USP 15 grams (Carton label)



Nystatin Ointment, USP 30 grams (Tube label)



Nystatin Ointment, USP 30 grams (carton label)



NYSTATIN

nystatin ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13668-534
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
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	yellow (Pale yellow to yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13668-534-01	15 g in 1 TUBE; Type 0: Not a Combination Product	01/29/2019	
2	NDC:13668-534-02	30 g in 1 TUBE; Type 0: Not a Combination Product	01/29/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211838	01/29/2019	

Labeler - Torrent Pharmaceuticals Limited (650175722)

Registrant - Torrent Pharma, Inc. (790033935)

Establishment

Name	Address	ID/FEI	Business Operations
Torrent Pharmaceuticals Limited		650537058	analysis(13668-534) , manufacture(13668-534) , pack(13668-534)

Revised: 12/2024

Torrent Pharmaceuticals Limited