

**NYSTATIN- nystatin ointment ointment  
Cosette Pharmaceuticals, Inc.**

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**Nystatin Ointment, USP**

**100,000 USP Nystatin Units p er Gram**

**For Topical Use Only. Not For Ophthalmic Use.**

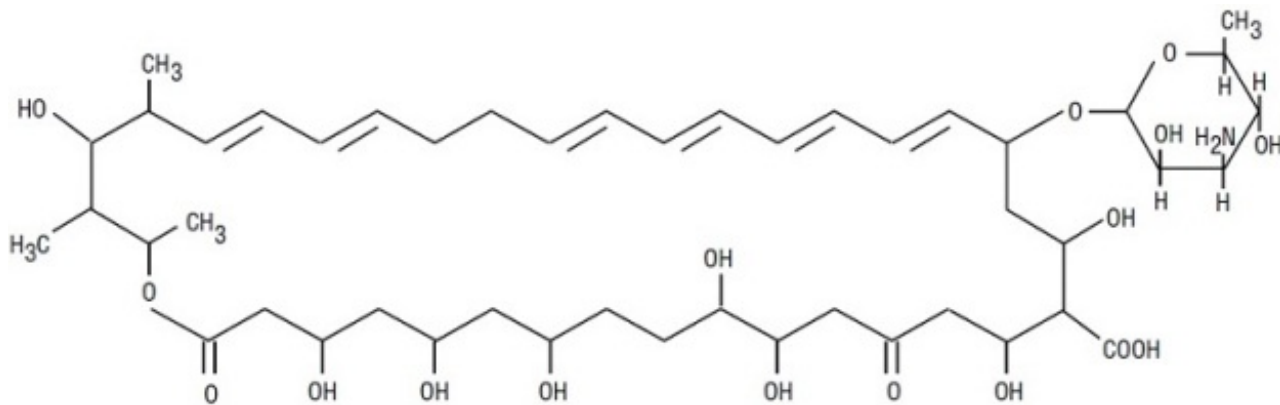
**Rx Only**

**DESCRIPTION**

Nystatin Ointment, USP is for dermatologic use. Nystatin Ointment, USP for topical use only, contains 100,000 USP nystatin units per gram, in a white petrolatum base.

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

The structural formula is as follows:



Molecular Weight 926.13

Molecular Formula C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub>

**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 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, USP is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

**Nystatin Ointment, USP 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 THE PATIENT**

**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.**)

**To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **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 USP Nystatin Units per gram) is a light yellow to yellow ointment available as follows:

NDC 0713-0686-15 15 gram tube

NDC 0713-0686-31 30 gram tube

**Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].**

**Distributed by:**

Cosette Pharmaceuticals, Inc.  
South Plainfield, NJ 07080

8-0686CPLNC3

Rev.03/2022

VC7623

**PRINCIPAL DISPLAY PANEL**

**NDC 0713-0686-15**

**Nystatin Ointment, USP**

**100,000 USP Nystatin Units Per Gram**

**15 g**

**Rx only**

**FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**Cosette Pharmaceuticals, Inc.**



**NDC 0713-0686-31**

**Nystatin Ointment, USP**

**100,000 USP Nystatin Units Per Gram**

**30 g**

**Rx only**

**FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**Cosette Pharmaceuticals, Inc.**



## NYSTATIN

nystatin ointment ointment

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0713-0686
<b>Route of Administration</b>	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
PETROLATUM (UNII: 4T6H12BN9U)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0686-15	1 in 1 CARTON	07/30/2018	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0713-0686-31	1 in 1 CARTON	07/30/2018	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209114	10/06/2017	

**Labeler** - Cosette Pharmaceuticals, Inc. (116918230)

**Registrant** - Cosette Pharmaceuticals, Inc. (116918230)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals NC Laboratories, LLC		079419931	analysis(0713-0686) , label(0713-0686) , manufacture(0713-0686) , pack(0713-0686)

Revised: 11/2023

Cosette Pharmaceuticals, Inc.