NYAMYC- nystatin powder
Upsher-Smith Laboratories, LLC

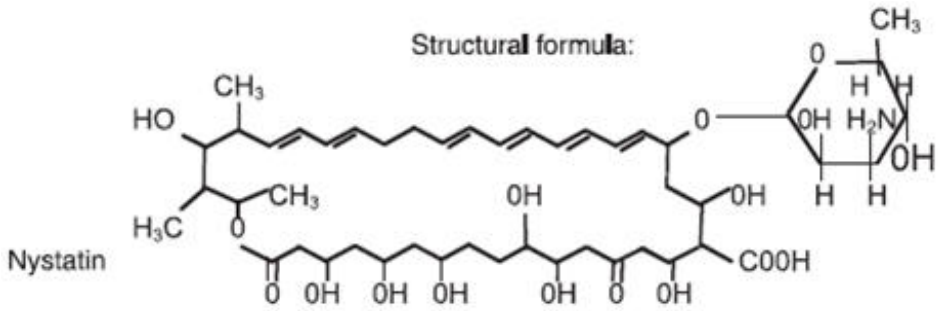
Nyamyc®
(Nystatin Topical Powder, USP)

100,000 units per gram
Rx only

FOR TOPICAL USE ONLY • NOT FOR OPHTHALMIC USE

DESCRIPTION

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



Nyamyc® (Nystatin Topical Powder, USP) is for dermatologic use.

Nyamyc® (Nystatin Topical Powder, USP) contains 100,000 USP nystatin units per gram dispersed in talc.

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 levels 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

Nyamyc® (Nystatin Topical Powder, USP) is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida albicans* and other susceptible *Candida* species.

Nyamyc® (Nystatin Topical Powder, USP) is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS

Nyamyc® (Nystatin Topical Powder, USP) is contraindicated in patients with a history of hypersensitivity to **any** of its components.

PRECAUTIONS

General

Nyamyc® (Nystatin Topical Powder, USP) 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 this medication should receive the following information and instructions:

1. The patient should be instructed to use this medication as directed (including the replacement of missed doses). This medication is not for any disorder other than that for which it is 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

Animal reproduction studies have not been conducted with any nystatin topical preparation. It also is not known whether theses preparations can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. **Nyamyc®** (Nystatin Topical Powder, USP) 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**].*

Geriatric Use

Clinical studies with nystatin topical powder did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

The frequency of adverse events reported in patients using nystatin topical 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

Very moist lesions are best treated with the topical dusting powder.

Adults and Pediatric Patients (Neonates and Older)

Apply to candidal lesions two or three times daily until healing is complete. For fungal infection of the feet caused by *Candida* species, the powder should be dusted on the feet, as well as, in all foot wear.

HOW SUPPLIED

Nyamyc® (Nystatin Topical Powder, USP) 100,000 units nystatin per gram is available as follow:

Bottles of 15 g (NDC 0832-0465-15)
Bottles of 30 g (NDC 0832-0465-30)
Bottles of 60 g (NDC 0832-0465-60)

STORAGE

Nyamyc® (Nystatin Topical Powder, USP)

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat (40°C/104°F). Keep tightly closed. Keep out of reach of children.

Nyamyc is a registered trademark of Upsher-Smith Laboratories, LLC.

Manufactured by
UPSHER-SMITH LABORATORIES, LLC
Maple Grove, MN 55369

Revised: 6/2020

PRINCIPAL DISPLAY PANEL - 15 gram Bottle Carton

NDC 0832-0465-15
Nyamyc®
Nystatin Topical Powder, USP

100,000 USP
units per gram

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NET WT. 15 grams
Rx only

UPSHER-SMITH

NYAMYC
nystatin powder

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0832-0465
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:0832-0465-15	1 in 1 CARTON	05/03/2005	
1		15 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0832-0465-30	1 in 1 CARTON	05/03/2005	
2		30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0832-0465-60	1 in 1 CARTON	03/09/2012	
3		60 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065183	05/03/2005	

Labeler - Upsher-Smith Laboratories, LLC (809088862)

Revised: 6/2020 Upsher-Smith Laboratories, LLC