

Safety Data Sheet

Nystatin and Triamcinolone Acetonide Ointment, USP

Strength: 100,000 USP

Pack Size: 15 gm,

NDC 72578-088-01,

Nystatin units and 1 mg

30 gm,

72578-088-04,

Triamcinolone Acetonide, USP

60 gm.

72578-088-02

Revision No.: 00

Emergency Overview

Nystatin and Triamcinolone Acetonide Ointment, USP for dermatologic use contain the antifungal agent nystatin and the synthetic corticosteroid triamcinolone acetonide. for external use only. Not for ophthalmic use.

Section 1 : Identification

Product Name:

Nystatin and Triamcinolone Acetonide Ointment, USP

Formula:

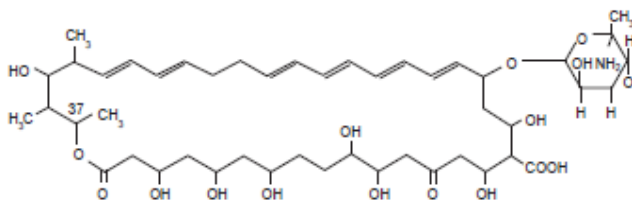
Nystatin USP: C₄₇H₇₅NO₁₇

Triamcinolone acetonide, USP: C₂₄H₃₁FO₆

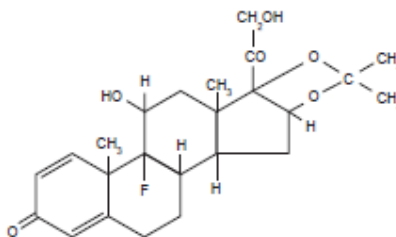
Chemical Name:

Nystatin USP:

(1*S*,3*R*,4*R*,7*R*,9*R*,11*R*,15*S*,16*R*,17*R*,18*S*,19*E*,21*E*,25*E*,27*E*,29*E*,31*E*,33*R*,35*S*,36*R*,37*S*)-33-[(2*S*,3*R*,4*R*,5*R*,6*S*)-4-amino-3,5-dihydroxy-6-methyl-oxan-2-yl]oxy-1,3,4,7,9,11,17,37-octahydroxy-15,16,18-trimethyl-13-oxo-14,39-dioxabicyclo[3.3.1]nonatriaconta-19,21,25,27,29,31-hexaene-36-carboxylic acid



Triamcinolone Acetonide: 9-fluoro-11 β , 16 α , 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17-acetal with acetone



Molecular Weight: Nystatin: 926.13 g/mol

Triamcinolone Acetonide: 434.50 g/mol

Description: Nystatin and Triamcinolone Acetonide Ointment, USP for dermatologic use contain the antifungal agent nystatin and the synthetic corticosteroid triamcinolone acetonide.

Nystatin, USP is a polyene antimycotic obtained from *Streptomyces noursei*. It is a yellow or slightly brownish powder hygroscopic with characteristics odor. It is freely soluble in dimethylformamide, slightly soluble in methanol, practically insoluble in water, alcohol and ether.

Dosage forms and strengths: A thin film of Nystatin and Triamcinolone Acetonide Ointment is usually applied to the affected areas twice daily in the morning and evening. The preparation should be discontinued if symptoms persist after 25 days of therapy.

Nystatin and Triamcinolone Acetonide Ointment should not be used with occlusive dressings.

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Triamcinolone Acetonide, USP 60 gm. 72578-088-02 Revision No.: 00

Manufacturer / supplier identification

Company Cadila Healthcare Ltd. Ahmedabad, India
Address Zydus Cadila, Topical Formulation facility. Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India

Contact for information Tel.:+91 2717-616430 Fax: +91 2717-616430

Emergency Telephone No Tel.:+91 2717-616401

Recommended use / Therapeutic Category Nystatin and Triamcinolone Acetonide Ointment, USP for dermatologic use contain the antifungal agent nystatin and the synthetic corticosteroid triamcinolone acetonide. For external use only. Not for ophthalmic use.

Restriction on Use / Contraindications These preparations are contraindicated in those patients with a history of hypersensitivity to any of their components.

Section 2 : Hazard (s) Identification

Dose and Administration A thin film of Nystatin and Triamcinolone Acetonide Ointment is usually applied to the affected areas twice daily in the morning and evening. The preparation should be discontinued if symptoms persist after 25 days of therapy. Nystatin and Triamcinolone Acetonide Ointment should not be used with occlusive dressings.

Adverse effects A single case (approximately one percent of patients studied) of acneiform eruption occurred with use of combined nystatin and triamcinolone acetonide in clinical studies. Nystatin is virtually nontoxic and nonsensitizing and is well tolerated by all age groups, even during prolonged use. Rarely, irritation may occur. The following local adverse reactions are reported infrequently with topical corticosteroids (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, perioral secondary infection, skin atrophy, striae and miliaria.

Over Dose Effect Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**, General); however, acute overdosage and serious adverse effects with dermatologic use are unlikely.

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Pregnancy Comments

There are no teratogenic studies with combined nystatin and triamcinolone acetonide. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Therefore, any topical corticosteroid preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Topical preparations containing corticosteroids should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers

It is not known whether any component of this preparation is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised during the use of this preparation by a nursing woman.

Pediatric Use

In clinical studies of a limited number of pediatric patients ranging from two months through 12 years, nystatin and triamcinolone acetonide cream formulation cleared or significantly ameliorated the disease state in most patients.

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation.

Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

Chronic corticosteroid therapy may interfere with the growth and development of children.

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Section 3: Composition / information on ingredients

Each gram contains: Each gram of Nystatin and Triamcinolone Acetonide Ointment provides 100,000 USP Nystatin units and 1 mg Triamcinolone Acetonide, USP in an ointment base of mineral oil and white petrolatum.

Section 4: First -aid measures

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Skin contact Wash exposed areas with plenty amounts of water and remove all the occluded cream from the skin. Extra care needs to be taken to clean folds, crevices, creases and groin. If adverse skin reactions occur, discontinue use. Seek medical attention.

Eye contact Immediately flush with plenty amounts of water for at least 15 minutes. Immediately remove any occlusion of the cream with plenty of water. If irritation continues, seek medical attention.

Ingestion Flush out mouth with water, consult a physician immediately.

Section 5: Fire -fighting measures

Fire and Explosion Hazards Assume that this product is capable of sustaining combustion.

Extinguishing Media Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.

Special Firefighting Procedures For single units (packages): No special requirements needed.

For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus.

Hazardous Combustion Products Hazardous combustion or decomposition products are expected when the product is exposed to fire.

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Section 6: Accidental Release Measures

Personal Precautions

Avoid excessive contact and contact with eyes. Wear safety goggles or shield.

Environmental Precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods

This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

Section 7: Handling and Storage

Handling

Handle in accordance with product label and/or product insert information.

Storage

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

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Section 8: Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and chemical properties

| | |
|------------------------------------|-------------------|
| Colour | White. |
| Physical State (liquid/solid/gas): | Semi-solid |
| Pack Style | 15 g, 30 g, 60 g. |

Section 10: Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate carcinogenic or mutagenic potential, or possible impairment of fertility in males or females.

Section 12: Ecological information

No relevant studies identified.

Section 13: Disposal consideration

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

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Section 15: Regulatory information

Generic Medicine. NDC no.: 72578-088-01 (15 gm), 72578-088-04 (30 gm), 72578-088-02 (60 gm).

Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Date of issue: 29/06/2020

Supersedes edition: New Edition