NYSTATIN

MYCONIL

Rx

100,000 IU/mL
Oral Suspension
(Oral Drops)
Antifungal

DESCRIPTION
Yellowish flavored suspension filled in Amber colored PET bottle.

FORMULATION:
Each mL contains:
Nystatin B.P ..... 100,000 IU (equivalent to 16.6667 mg)

PHARMACOKINETICS:
Nystatin is poorly absorbed from the gastrointestinal tract. It is not absorbed through the skin or mucous membranes when applied topically.

INDICATION:
Used for the prophylaxis and treatment of candidiasis of the skin and mucous membrane.

DOSAGE AND ADMINISTRATION:
Oral Suspension:
In infants and children: 100,000 units or more may be given 4 times daily. For the treatment of lesions of the mouth: 100,000 units 4 times daily. For the treatment of immuno compromised patients:
500,000 units 4 times daily. A prophylactic dose for infants born to mothers with vaginal candidiasis: 100,000 units daily The formulation should be kept in contact with the affected area for as long as possible, and patients should avoid taking food or drink for one hour after dose.

Candidiasis:
A systematic review of 14 studies (12 of prophylaxis, 2 of treatment) considered that Nystatin could not be recommended for prophylaxis or treatment of Candida infections in patients with immunosuppression.

Antimicrobial Action:
Nystatin is a polyene antifungal antibiotic that interferes with the permeability of the cell membrane of sensitive fungi by binding to sterols, chiefly ergosterol. Its main action is against Candida spp.

PRECAUTIONS:
Some intervaginal preparations of Nystatin may damage latex contraceptives and additional contraceptive precautions may be necessary during treatment.

CONTRAINDICATIONS:
It is contraindicated to persons with allergies to Nystatin.

ADVERSE EFFECTS:
Nausea, vomiting, and diarrhea have occasionally been reported after oral use of Nystatin. Oral irritation or sensitization may occur. Rashes, including urticaria have occurred, and Stevens-Johnson syndrome has been reportedly rarely. Irritation may occur rarely after the topical use of Nystatin.

Effects in the skin
Generalized pustular eruptions were reported in a patients after oral Nystatin subsequent sensitivity testing revealed delayed (type IV) hypersensitivity to Nystatin.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of benefit of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reaction.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding to 30°C.

AVAILABILITY:
Boston round amber bottle with pilfer proof aluminum cap (printed Amson Logo) and medicine plastic dropper x 30ml. (Box of 1's).
FDA Registration Number : DRP-7275
Date of First / Renewal of Authorization:
13 November 2019

Date of Revision of Package Insert:
01 September 2022

AMSON

Manufactured by:
AMSON VACCINES & PHARMA (PVT) LTD.
Plot No. 154, Industrial Triangle, Kahuta Road,
Islamabad - Pakistan.
ISO 9001, 14001 & 45001 Certified.

SAHAR

Imported & Distributed by:
SAHAR INTERNATIONAL TRADING, INC.
354 Aguirre Ave. Phase III, BF Homes
Parañaque City, Philippines

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