

DESENEXT- miconazole nitrate powder
Novartis Consumer Health, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- cures most athlete's foot (tinea pedis)
- relieves itching, burning, cracking and discomfort associated with athlete's foot

Warnings

For external use only

Do Not Use

- in the eyes
- for nail or scalp infections

When using this product

- do not get into the eyes

Stop use and ask a doctor if

- irritation occurs or gets worse.
- no improvement within 4 weeks

Keep Out of Reach of Children

If swallowed, get medical help or contact a poison control center right away.

Directions

- adults and children 2 years and older
- wash the affected area with soap and water and dry completely before applying
- apply a thin layer over affected area twice a day (morning and night) or as directed by a doctor
- supervise children in the use of this product
- pay special attention to the spaces between the toes. Wear well-fitting, ventilated shoes, and change shoes and socks at least once a day
- use every day for 4 weeks
- children under 2 years of age: ask a doctor

Other information

- store at controlled room temperature 20-25C (68-77F)
- See container bottom for lot number and expiration date

Inactive ingredients

corn starch, fragrance, talc

Questions or comments?

call **1-800-452-0051**

Distributed by:

Novartis Consumer Health, Inc.

Parsippany, NJ 07054-0622

Principal Display Panel

NDC 0067-0949-30

2% Miconazole Nitrate, Antifungal

Desenex®

Powder

Absorbs Wetness

Cures Most Athlete's Foot

Relieves Itching & Burning

Principal Display

NDC 0067-0949-30

Prescription Strength

Desenex[®]

2% MICONAZOLE NITRATE,
ANTIFUNGAL

**Absorbs
Wetness**



**CURES
MOST
ATHLETE'S
FOOT**

**RELIEVES ITCHING &
BURNING**

Powder

NET WT. 3 oz (85g)

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PRODUCT PACKAGED BY WEIGHT NOT VOLUME

DESENEX

miconazole nitrate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0067-0949
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0067-0949-15	43 g in 1 CONTAINER		
2	NDC:0067-0949-30	85 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/03/2009	

Labeler - Novartis Consumer Health, Inc. (879821635)

Revised: 12/2012

Novartis Consumer Health, Inc.