

ANTIFUNGAL- miconazole nitrate cream
Proficient Rx LP

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.

Miconazole Nitrate Cream - Antifungal Cream

Drug Facts

Active ingredient

Miconazole nitrate, USP 2%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most athlete's foot, jock itch and ringworm
- for effective relief of itching, scaling, cracking, burning and discomfort

Warnings

For external use only

Do not use on children under 2 years of age unless directed by a doctor.

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 4 weeks (for athlete's foot and ringworm) or within 2 weeks (for jock itch)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wash the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night), or as directed by a doctor
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated

shoes, and change shoes and socks at least once daily

- for athlete's foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks
- if condition lasts longer, contact a doctor
- this product is not effective on the scalp or nails

Other information

- store at controlled room temperature 59°-86°F (15°-30°C).
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

benzoic acid, butylated hydroxyanisole, mineral oil, oleoyl polyoxylglycerides, pegoxol 7 stearate, purified water

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday- Friday.

Distributed by: **Actavis**

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

Principal Display Panel

NDC 63187-885-15

Compare to the active ingredient in Micatin[®] Antifungal Cream*

Antifungal Cream

Miconazole Nitrate Cream, USP 2%

Soothes Itching, Scaling, Cracking, and Burning

Cures Most Athlete's Foot, Jock Itch & Ringworm

Net wt. 0.5 oz (14g)



NDC 63187-885-15

Lot # 00000
Exp. 00/00/00
SN# MASTER

Miconazole Nitrate 2%

0.5 oz (14g) CreamEach tube contains: Miconazole Nitrate, USP 2%
Antifungal

See box

Product ID: RM088515

For external use only

Dist. By: Actavis Pharma, Inc. Parsippany, NJ 07054 USA Made in India

Store at controlled room temperature 59°-86°F (15°-30°C) Keep medication out of the reach of children

Miconazole Nitrate 2%
0.5 oz (14g) Cream
Lot #:00000 SN#MASTER
NDC 63187-885-15 Exp:00/00/00Miconazole Nitrate 2%
0.5 oz (14g) Cream
Lot #:00000 SN#MASTER
NDC 63187-885-15 Exp:00/00/00Miconazole Nitrate 2%
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NDC 63187-885-15 Exp:00/00/00Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320

ANTIFUNGAL

miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-885(NDC:0472-0735)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-885-15	1 in 1 CARTON	09/01/2017	
1		14 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
OTC monograph final	part333C	05/01/2007	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-885)

Revised: 11/2019

Proficient Rx LP