

ANTI-FUNGAL- tolnaftate powder
Rij Pharmaceutical Corporation

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.

Anti-Fungal Powder

Active Ingredient

Tolnaftate 1 %

Purpose

Antifungal

Uses

- for effective treatment of most athlete's foot (tinea pedis) and jock itch (tinea cruris)
- relieves itching, scaling, burning, irritation and discomfort
- clears up most athlete's foot infection and, with daily use, helps to keep it from coming back

Warnings

For external use only

Do not use on children under 2 years of age.

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) 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

- shake well before use
- clean 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
- this product is not effective on the scalp or nails

For athletes foot

- use daily for 4 weeks
- pay special attention to the spaces between the toes
- wear well-fitting, ventilated shoes
- change shoes and socks at least once a daily

- to prevent athlete's foot: clean and dry feet thoroughly, apply once or twice daily

For jock itch

- use daily for 2 weeks

Other information

store between 2° - 30° C (36° - 86° F)

Inactive ingredients

starch, talc

Package Label Display

Drug Facts

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NDC 53807-123-45

TOLNAFTATE

ANTIFUNGAL POWDER

1%

Cures Athlete's Foot and Jock Itch Fungi

Net Wt. 45 g. (1 1/2 OZ.)

COMPARE TO ACTIVE INGREDIENT IN TINACTIN®

Drug Facts (continued)

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*This product is not manufactured or distributed by the owner of the registered trademark Tinactin®.



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40 COMMERCIAL AVENUE
Middletown, NY 10941
Rev. 11/08

ANTI-FUNGAL

tolnaftate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	.45 g in 45 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:53807-123-45	45 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-123)

Revised: 4/2018

Rij Pharmaceutical Corporation