

XTRACARE ANTIFUNGAL FOOT- tolnaftate spray

Rejoice International

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.

XtraCare Antifungal Foot

☐Active Ingredient Purpose

Tolnaftate 1% Antifungal

☐Use

- cures most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- if used daily, can prevent recurrence of athlete's foot
- relieves symptoms of athlete's foot, including itching, burning and cracking

☐Keep out of reach of children. ☐If swallowed, get medical help or contact a Poison Control Center immediately. Do not use on children under 2 years of age unless directed by a doctor.

XtraCare® Antifungal Foot Spray

For Athlete's Foot

Tolnaftate 1%

- Relieves Itching & Burning
- Cures & Prevents Most Athlete's Foot
- Fights Odor All Day

*Compare to the Active Ingredient in Tinactin®

CAUTION Contents under pressure - Read precautions on back panel.

Net Wt 3.5 Oz (100g)

☐Warnings

For external use only.

Flammable. ☐Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120oF (49oC).

☐When using this product

- avoid eyes & face
- use only as directed. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement after 4 weeks

☐Directions

- wash affected area and dry thoroughly
- shake can well and spray a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot: pay special attention to spaces between the toes; wear well-fitted, ventilated shoes and change shoes and socks at least once a day.

- use daily for 4 weeks; if condition persists longer, consult a doctor
- to prevent athlete's foot, apply once or twice daily (morning and night)
- in case of clogging, clean nozzle with a pin

❑ Inactive Ingredients

butane, propane, alcohol, butylated hydroxytoluene, talc.

❑ **Other information** ❑ store between 68o to 77oF (20o to 25oC)

❑ **Questions/Comments?** ❑ 1-855-345-5575

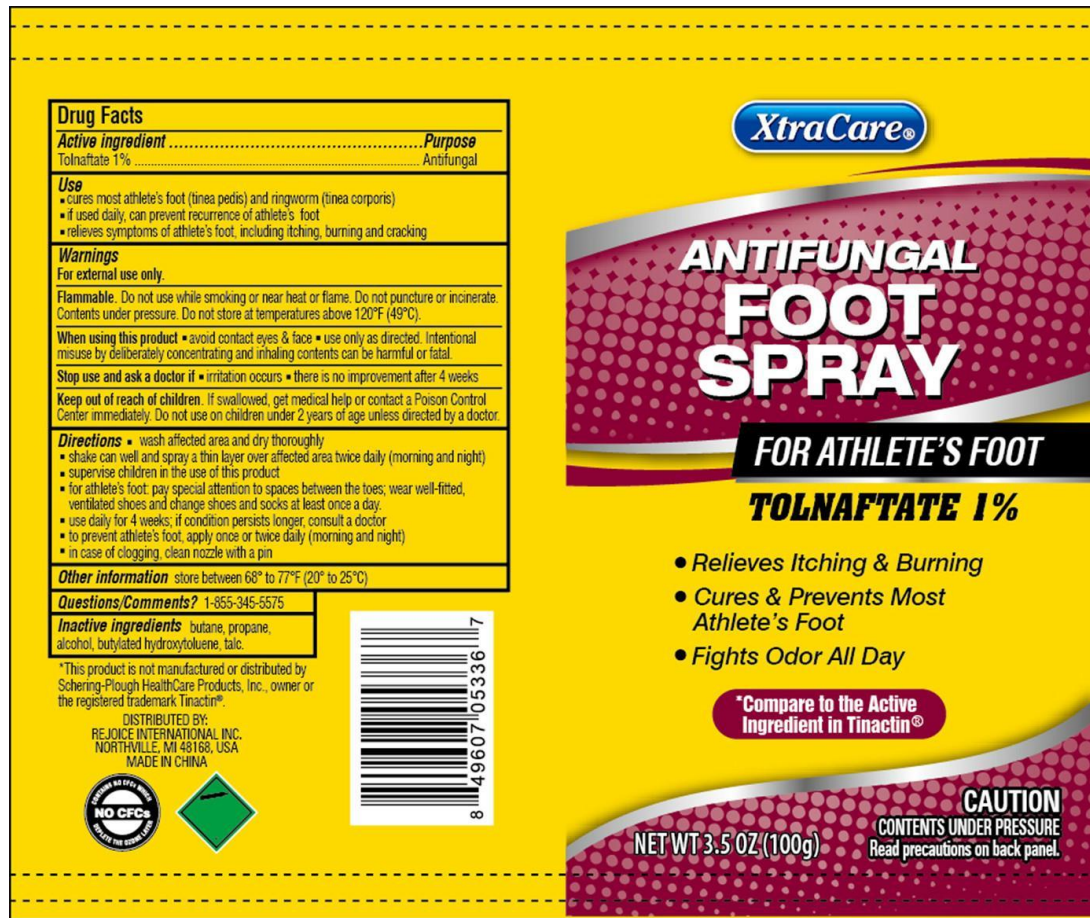
*This product is not manufactured or distributed by Schering-Plough HealthCare Products, Inc., owner of the registered trademark Tinactin®

DISTRIBUTED BY

REJOICE INTERNATIONAL, INC

NORTHVILLE, MI 48168 USA

MADE IN CHINA



XTRACARE ANTIFUNGAL FOOT

tolnaftate spray

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:57337-056

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTANE (UNII: 6LV4FOR43R)	
PROPANE (UNII: T75W9911L6)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-056-01	100 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/11/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	02/11/2014	

Labeler - Rejoice International (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ludao Cosmetics Co., Ltd.		679885595	manufacture(57337-056)

Revised: 9/2019

Rejoice International