

TOLNAFTATE- tolnaftate cream
Valu Merchandisers, Co.

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.

Best Choice Tolnaftate 1% Cream

Active ingredient (in each gram)

Tolnaftate 1%

Purpose

Antifungal

Uses

- clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis)
- helps prevent most athlete's foot from recurring when used daily
- effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking

Warnings

For external use only

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

Do not use

on children under 2 years of age except under the advice and supervision of a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- 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

- use daily for 4 weeks; if condition persists longer, ask a doctor
- to prevent athlete's foot, apply once or twice daily (morning and/or night)
- this product is not effective on the scalp or nails

Inactive ingredients

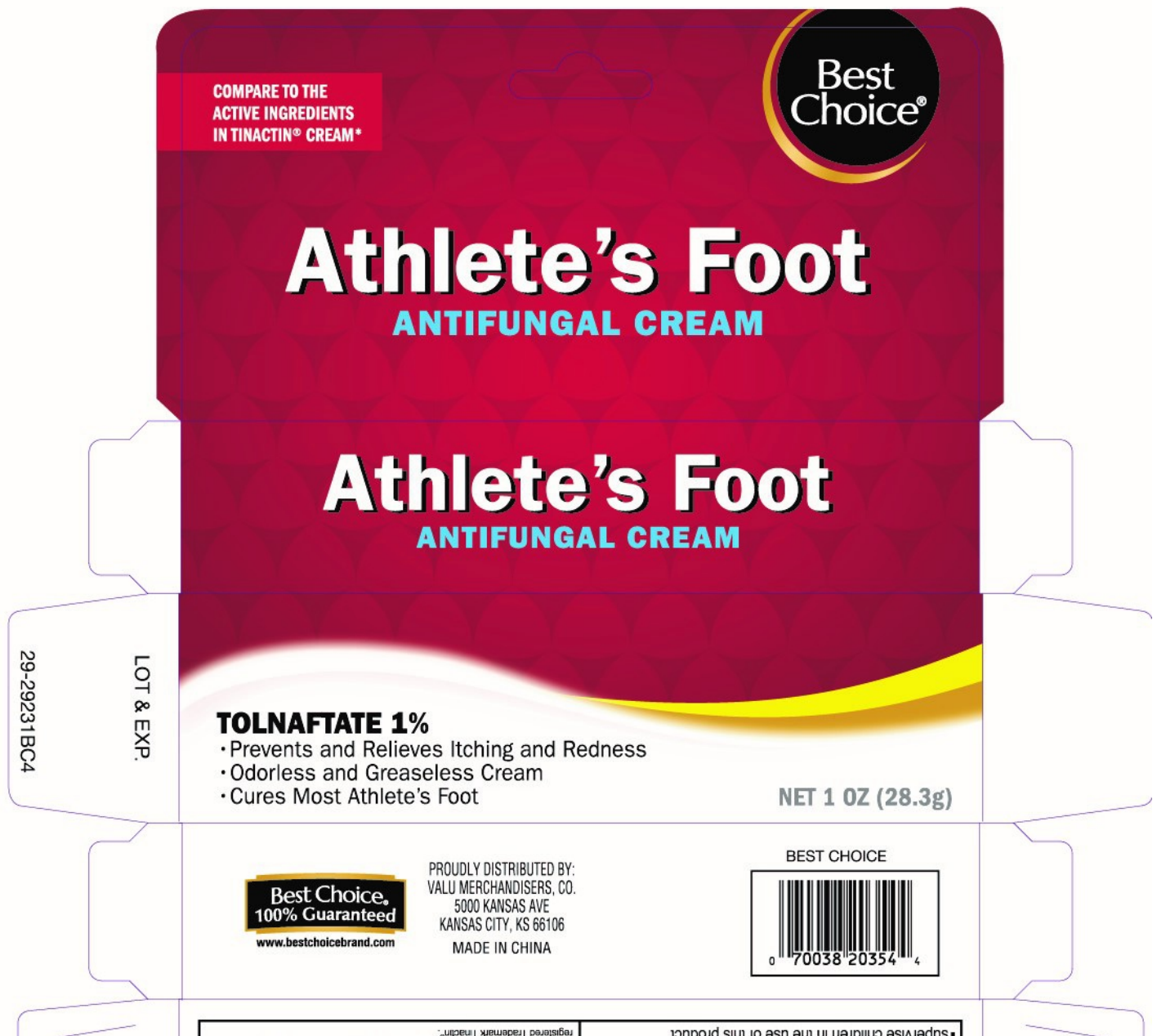
cetyl alcohol, ethylparaben, glycerin, glyceryl stearate, mineral oil, petrolatum, polysorbate 80, purified water, sodium lauryl sulfate

Other information

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

Package label

Best Choice Tolnaftate 1%



Drug Facts	
Active ingredient (in each gram)	Tolnaftate 1% Antifungal
Uses	<ul style="list-style-type: none"> • clinically proven to cure most athlete's foot (tinea pedis) and ringworm (tinea corporis) • helps prevent most athlete's foot from recurring when used daily • effectively soothes and relieves symptoms of athlete's foot, including itching, burning and cracking
Warnings	<ul style="list-style-type: none"> • For external use only • When using this product avoid contact with the eyes • Irritation occurs • there is no improvement within 4 weeks
Directions	<ul style="list-style-type: none"> • wash affected area and dry thoroughly • apply a thin layer over affected area twice daily (morning and night)
Keep out of reach of children.	If swallowed, get medical help or contact a Poison Control Center right away.
Do not use	on children under 2 years of age except under the advice and supervision of a doctor.
Stop use and ask a doctor if	irritation occurs
Inactive ingredients	cetyl alcohol, ethylparaben, glycerin, glyceryl stearate, mineral oil, petrolatum, polysorbate 80, purified water, sodium lauryl sulfate
Other information	<ul style="list-style-type: none"> • store between 2° and 30°C(36° and 86°F)
Drug Facts (continued)	<ul style="list-style-type: none"> • 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 • use daily for 4 weeks; if condition persists longer, ask a doctor • to prevent athlete's foot, apply once or twice daily (morning and/or night) • this product is not effective on the scalp or nails

TOLNAFTATE

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-354
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
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLPARABEN (UNII: 14255EXE39)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-354-01	1 in 1 BOX	03/02/2012	
1		28 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	03/01/2012	

Labeler - Valu Merchandisers, Co. (868703513)

Revised: 2/2023

Valu Merchandisers, Co.