

TRITOLNACIDE C- tolnaftate cream
Trifluent Pharma LLC

TRITOLNACIDE™ C

Drug Facts

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- Cures most Athlete's Foot (Tinea Pedis), Jock Itch (Tinea Cruris), and Ringworm (Tinea Corporis)
- Relieves itching, cracking, burning, and scaling, which accompany these conditions
- Clinically proven to prevent most Athlete's Foot (Tinea Pedis) with daily use
- Clears up most Athlete's Foot (Tinea Pedis) infection and with daily use helps keep it from coming back

Warnings

For external use only

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

Ask a physician or pharmacist before use if you are using any other medicines or cleansers on your skin

When using this product

- Avoid contact with eyes: rinse immediately with cool tap water if contact occurs
- Do not use for vaginal yeast

Stop use and ask a physician if irritation occurs or if there is no improvement within 4 weeks (for Athlete's Foot or 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 (1-800-222-1222) right away.

Directions

- Wash the affected area with soap and water and dry thoroughly
- Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a physician
- 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 persists longer, consult a physician
- This product is not effective on the scalp or nails
- To prevent Athlete's Foot, wash the feet and dry thoroughly; apply a thin layer of the product to the feet once or twice daily (morning and/or night)
- Wash hands after each use

Other information

Store at room temperature 20-28°C (68 - 82°F); do not store in extreme heat

Inactive ingredients

Alkyl (C12-15) Benzoate, Butylparaben, Carica Papaya (Papaya) Fruit Extract, Carthamus Tinctorius (Safflower) Seed Oil, Cetyl Alcohol, Chamomilla Recutita (Matricaria) Flower Extract, Dimethicone, Emulsifying Wax, Ethylparaben, Glycerin, Glycerol Stearate, Hydrogenated Polydecene, Isobutylparaben, Melaleuca Alternifolia (Tea Tree) Oil, Methylparaben, PEG 100 Stearate, Phenoxyethanol, Polyethylene Glycol 400, Propylene Glycol, Propylparaben, Purified Water, Sodium Polyacrylate, Trideceth-6, Xanthan Gum

Questions/Comments?

(210) 944-6920

PRINCIPAL DISPLAY PANEL - 37 mL Pouch Tube Label

Tear at notch to open. Do not use if seal is broken.

PRODUCT SHOULD BE ADMINISTERED UNDER THE
SUPERVISION OF A LICENSED MEDICAL PRACTITIONER

TRIFLUENT
PHARMA™

TriTolnacide™ C

TOLNAFTATE

ANTIFUNGAL CREAM
NDC 73352-561-10

1.25 FL. OZ. (37 mL)

Tear at notch to open. Do not use if seal is broken.

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Drug Facts (continued)

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ISOBUTYLPARABEN, METHYLGLUCYL DIMETHYLUMINA (100-1100) UN, Methylparaben, PEG 100 Stearate, Phenoxyethanol, Polyethylene Glycol 400, Propylene Glycol, Propylparaben, Purified Water, Sodium Polyacrylate, Trideceth-6, Xanthan Gum

Questions/Comments?
(210) 944-6920

MANUFACTURED IN THE U.S.A.

MANUFACTURED FOR:
Trifluent Pharma, LLC
San Antonio, TX 78213

561-10
REV01 06/24



TRITOLNACIDE C

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73352-561
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 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PAPAYA (UNII: KU94FIY6JB)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)
ISOBUTYLPARABEN (UNII: 0QJ25X58G)
TEA TREE OIL (UNII: VIF565UC2G)
METHYLPARABEN (UNII: A2I8C7HI9T)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0KO0R)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)
TRIDECETH-6 (UNII: 3T5PCR2H0C)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73352-561-10	1 in 1 POUCH	06/17/2024	
1		37 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M005	06/17/2024	

Labeler - Trifluent Pharma LLC (117167281)

Revised: 6/2024

Trifluent Pharma LLC