

TRITOLNACIDE S- tolnaftate solution
Trifluent Pharma LLC

TriTolnacide™ S

DRUG FACTS

ACTIVE INGREDIENT

Tolnaftate 1%

PURPOSE

Antifungal

USES

- Treats most Athlete's Foot (Tinea Pedis), Jock Itch (Tinea Cruris), and Ringworm (Tinea Corporis)
- Relieves discomfort, irritation, cracking, scaly skin between the toes and itching, burning feet.

WARNINGS

For external use only.

Ask a doctor 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 doctor 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.

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

DIRECTIONS

- Wash the affected area with soap and water and dry thoroughly
- Apply a thin layer of the product over the affected area twice daily (morning and night), or as directed by a doctor
- 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

- Supervise children in the use of this product
- 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 doctor
- This product is not effective on the scalp or nails
- Wash hands after each use

INACTIVE INGREDIENTS

Butylparaben, butylated hydroxyanisole, butylated hydroxytoluene, Carthamus tinctorius (safflower) seed oil, ethylparaben, isobutylparaben, methylparaben, Origanum vulgare (oregano) leaf oil, phenoxyethanol, propylparaben, Simmondsia chinensis (jojoba) seed oil, tocopherol, white mineral oil.

QUESTIONS OR COMMENTS?

CALL (210) 944-6920

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Label

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

TRIFLUENT
PHARMA®

TriTolnacide™ S
ANTIFUNGAL SOLUTION

TOLNAFTATE

NDC 73352-560-01
0.5FL OZ (15 mL)

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



TriTolnacide™ S
ANTIFUNGAL SOLUTION

TOLNAFTATE

NDC 73352-560-01
0.5 FL OZ (15 mL)

Drug Facts

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 doctor • 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 • Supervise children in the use of this product • 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 doctor • This product is not effective on the scalp or nails • 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

Butylparaben, butylated hydroxyanisole, butylated hydroxytoluene, carthamus tinctorius (safflower) seed oil, ethylparaben, isobutylparaben, methylparaben, origanum vulgare (oregano) leaf oil, phenoxyethanol, propylparaben, simmondsia chinensis (jojoba) seed oil, tocopherol, white mineral oil

Drug Facts (cont)

ACTIVE INGREDIENT..... PURPOSE
Tolnaftate 1%.....Antifungal

USES

• Treats most Athlete's Foot (Tinea Pedis), Jock Itch (Tinea Cruris), and Ringworm (Tinea Corporis)
• Relieves discomfort, irritation, cracking, scaly skin between the toes and itching, burning feet

WARNINGS - For external use only

Ask a doctor 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 doctor 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.

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

MADE IN THE U.S.A.

QUESTIONS OR COMMENTS?
CALL (210) 944-6920

MANUFACTURED FOR:
Trifluent Pharma, LLC
San Antonio, TX 78213
Made In The U.S.A.

560-01
REV03 12-11-2023

SEE OPPOSITE PANEL FOR MORE INFORMATION

TRITOLNACIDE S

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73352-560
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.01 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
JOJOBA OIL (UNII: 724GKU717M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
OREGANO LEAF OIL (UNII: 7D0CGR40U1)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QOJ25X58G)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73352-560-01	15 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	12/11/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M005	12/11/2023	

Labeler - Trifluent Pharma LLC (117167281)

Revised: 12/2023

Trifluent Pharma LLC