TRIMAZOLE- clotrimazole cream Trifluent Pharma LLC

Trimazole ™

Drug Facts

Active ingredient

Clotrimazole 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.

Warnings

For external use only

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

Ask a doctor 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.

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).

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

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.
- Supervise children in the use of this product.
- For Athlete's Foot: pay special attention to spaces between 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 doctor.

- This product is not effective on the scalp or nails.
- Wash hands after each use.

Other information

Store at 15-30°C (59-86°F). Avoid excessive heat.

Do not use if product is damaged.

Inactive ingredients

Aloe barbadensis leaf extract, aminomethyl propanol, caprylic / capric triglyceride, cetyl alcohol, disodium EDTA, glyceryl stearate, hydroxypropylcellulose, Lavandula angustifolia (lavender) oil, Melaleuca alternifolia (tea tree) oil, methylparaben, PEG 100 stearate, polyethylene glycol 400, polysorbate 20, polysorbate 60, propylene glycol, propylparaben, purified water, stearic acid.

Questions/Comments?

(210) 944-6920

PRINCIPAL DISPLAY PANEL - 85 G Tube Pouch Label

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

NDC 73352-570-01

TRIFLUENT PHARMA™

Trimazole™

1% Clotrimazole

Topical Antifungal Cream

NET WT. 3 OZ. (85 G)

NDC 73352-570-01



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NET WT. 3 OZ. (85 G)

Drug Facts

Active IngredientPurpose
Clotrimazole 1%......Antifungal

Uses

Drug Facts (continued)

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Questions/Comments?

(210) 944-6920

MANUFACTURED FOR-

Trifluent Pharma, LLC San Antonio. TX 78213

MANUFACTURED IN THE U.S.A.

570-01 REV01 04/2024



TRIMAZOLE

clotrimazole cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73352-570

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active Plotety		
Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
LAVENDER OIL (UNII: ZBP1YXW0H8)				
TEA TREE OIL (UNII: VIF565UC2G)				
METHYLPARABEN (UNII: A218C7H19T)				
PEG-100 STEARATE (UNII: YD01N1999R)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
POLYSORBATE 60 (UNII: CAL22UVI4M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				
WATER (UNII: 059QF0KO0R)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:73352-570- 01	1 in 1 POUCH	06/10/2024				
1		85 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 DRUG	M005	06/10/2024		

Labeler - Trifluent Pharma LLC (117167281)

Revised: 6/2024 Trifluent Pharma LLC