

ROYCEDERM ANTIFUNGAL .SOAP.- clotrimazole 1% soap

RoyceDerm LLC

Initial Drug Listing - RoyceDerm ANTIFUNGAL SOAP- 168

Clotrimazole 1%

Anti-fungal

- For effective treatment of most athlete's foot(tinea pedis), ringworm(tinea corporis) and jock itch(tinea cruris).
- For effective relief of itching, burning and cracking skin.

For external use only.

Avoid contact with the eye.

Stop and ask a doctor if irritation occurs or if there is no improvement within 2 weeks for jock itch or within 4 weeks for athlete's foot & ringworm.

Do not use on children under 2 of age except under the advice and supervision of a doctor.

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

- Wash affected area well and let product sit 2-3 minutes before rinsing
- Make sure to dry affected area thoroughly.
- Supervise children in the use of this product.
- For Athlete's foot: pay special attention to the spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily.
- Use 1-2 times daily. Use daily for 4 weeks; if condition persists longer, ask a doctor.
- This product is not effective on the scalp or nails.

Store at room temperature 59°-86°F (15°-30°C).

Melaleuca Alternifolia (Tea Tree) Leaf Oil, Water, Sorbitol, Elaeis Guineensis (Palm) Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Propylene Glycol, Glycerin, Stearic Acid, Lauric Acid, Myristic Acid, Sodium Myristate, Monosodium Glutamate, Sodium Hydroxide, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide NP

- Visit www.roycederm.com
- Tel: +1(307)461-0958

RoyceDerm
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MADE IN CHINA

RoyceDerm
ANTIFUNGAL SOAP
TOLNAFTATE 1.0%
Advanced Defense Formula
Treats most Athlete's Foot, Jock Itch & Ringworm

Drug Facts
Active ingredient Tolnaftate 1% **Purpose** Anti-fungal
Uses For effective treatment of most athlete's foot (tinea pedis), ringworm (tinea corporis) and jock itch (tinea cruris). For effective relief of itching, burning and cracking skin.
Warnings For external use only. When using this product Avoid contact with the eye. Stop and ask a doctor if irritation occurs or if there is no improvement within 2 weeks for jock itch or within 4 weeks for athlete's foot & ringworm. Do not use on children under 2 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.

Drug Facts (continued)
Directions Wash the affected area and dry thoroughly. Lather and apply to affected area. Leave on for several minutes before rinsing thoroughly. Use 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 the 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, ask a doctor. This product is not effective on the scalp or nails.
Other information Store at room temperature 59°-86°F (15°-30°C).
Inactive ingredients Melaleuca Alternifolia (Tea Tree) Leaf Oil, Water, Sorbitol, Elaeis Guineensis (Palm) Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Propylene Glycol, Glycerin, Stearic Acid, Lauric Acid, Myristic Acid, Sodium Myristate, Monosodium Glutamate, Sodium Hydroxide, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide NP
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2 Bars 4 oz (113 g) Each Total Net Wt. 8oz (226g)

ROYCEDERM ANTIFUNGAL .SOAP.

clotrimazole 1% soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85424-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	2.26 g in 226 g

Inactive Ingredients

Ingredient Name	Strength
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0073W7L)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
CERAMIDE NP (UNII: 4370DF050B)	
LAURIC ACID (UNII: 1160N9NU9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
MONOSODIUM GLUTARATE (UNII: 36765054OO)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KOOR)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-019-01	226 g in 1 CARTON; Type 0: Not a Combination Product	03/26/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	03/26/2026	

Labeler - RoyceDerm LLC (130329531)

