ANTIFUNGAL MEDICATED BAR- tolnaftate soap
RoyceDerm LLC

Initial Drug Listing - RoyceDerm Tolnaftate 1% antifungal soap

Tolnaftate 1%

anti-fungal

- Cures & prevents most athlete's foot(tinea pedis), jock itch(tinea cruris) & ringworm (tinea corporis).
- Relieves itching, irritation, redness, scaling, and discomfort associated with these conditions.

For external use only

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

avoid contact with the eyes. If contact occurs, rinse the eyes thoroughly with water.

if condition worsens or does not improve after 4 weeks of regular use as directed.

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

- Wash the affected area thoroughly with water.
- Lather the soap and apply it to the affected area.
- Allow the lather to sit on the skin for 2-3 minutes before rinsing thoroughly.
- 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 1-2 times daily for 4 weeks; if the condition persists longer, consult a doctor.
- Supervise children in the use of this product.

- Store at room temperature.
- Protect from freezing.

Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aqua (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, Sodium Glutamate, Sodium Hydroxide, Sodium Dodecylbenzene Sulfonate, Sulfur, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide NP.

Visit at www.roycederm.com

ANTIFUNGAL MEDICATED BAR

tolnaftate soap

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85424-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	
LAURIC ACID (UNII: 1160N9NU9U)	
SODIUM GLUTAMATE (UNII: W81N5U6R6U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF WATER (UNII: 8FP93ED6H2)	
SORBITOL (UNII: 506T60A25R)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
WATER (UNII: 059QF0KO0R)	
CERAMIDE NP (UNII: 4370DF050B)	
SULFUR (UNII: 70FD1KFU70)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-001-01	232 g in 1 CARTON; Type 0: Not a Combination Product	04/20/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	04/20/2025	

Labeler - RoyceDerm LLC (130329531)

Revised: 3/2025 RoyceDerm LLC