

ATHLETE FOOT MEDICATED BAR- tolnaftate soap
Beautivity LLC

Initial Drug Listing - Athlete's Foot Soap Bar

Tolnaftate 1%

Antifungal

Helps relieve and prevent itching, burning, cracking, and scaling associated with fungal infections such as athlete's foot, jock itch, ringworm, and other skin irritations.

For external use only

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

When using this product avoid contact with eyes, if contact occurs, rinse thoroughly with water.

Stop use and ask doctor if irritation occurs, there is no improvement within 2 weeks.

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

- Wash affected area & dry thoroughly.
- Apply a thin layer over affected area twice daily (morning and night).
- Supervise children in the use of this product.
- Use daily for 2 weeks.

Aqua (Water), Melaleuca Alternifolia (Tea Tree) Leaf Oil, 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 Thermal Water, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide

Store at room temperature. Protect from excessive heat (above 104°F /40°C)

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ATHLETE FOOT MEDICATED BAR

tolnaftate soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85398-007
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 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
MYRISTIC ACID (UNII: 013V7S25AW)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	
GLYCERIN (UNII: PDC6A3COOX)	
LAURIC ACID (UNII: 1160N9NU9U)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	

SULFUR (UNII: 70FD1KFU70)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM GLUTAMATE (UNII: W81N5U6R6U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-007-01	232 g in 1 CARTON; Type 0: Not a Combination Product	08/18/2025	
2	NDC:85398-007-02	116 g in 1 CARTON; Type 0: Not a Combination Product	08/18/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/18/2025	

Labeler - Beautivity LLC (096573788)

Revised: 10/2025

Beautivity LLC