HERMON ATHLETES FOOT TOLNAFTATE 1% KIT- tolnaftate 1% kit Beautivity LLC

Initial Drug Listing - Hermon Athlete's foot Tolnaftate 1% kit

Soap Bar: Tolnaftate 1%Cream: Tolnaftate 1%

Antifungal

- cures most athlete's foot (tinea pedis)
- cures most jock itch(tinea cruris) and ringworm (tinea corporis)
- relieves itching, burning, cracking and scaling which accomppany these conditions
- For effective relief of itching, cirritation, redness, scaling, cracking, burning, soreness, and discomfort which can accompany these conditions.

For external use only

- on children under 2 years of age unless directed by a doctor.
- On nails or scalp
- in or near the mouth or eyes
- for vaginal yeast infections

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

if irritation occurs or there is no improvement within 2 wveeks.

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

Directions (Cream)

- adults and children 12 years and over
- use the tip of thecap to break the seal and open the tube
- · wash the affedted skin with soap and water and dry completely before applying
- for athlete's foot wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
- between the ttoes only: apply twice a day (morning and night) for 1 week or as directed by a doctor
- on the bottom or sides ofthe foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor
- for jock itch and ringworm: apply oncea day (morning or night) for 1 week or as directed by a doctor
- wash hands after each use
- children under 12 years: ask a doctor
- wash affected area and dry thoroughly
- apply a thin layer over affected area twice daily (morning and night)
- supervise children in the use of this product
- use daily for2 weeks

Directions (Soap Bar)

• Wet skin with warm water and lather soap.

- Gently massage onto affected areas.
- Rinse thoroughly and dry.
- Use twice daily or as directed by a doctor.

Do not use if seal on tube is broken or is not visible. Store at room temperature. Protect from excessive heat(above 104°F/40°C)

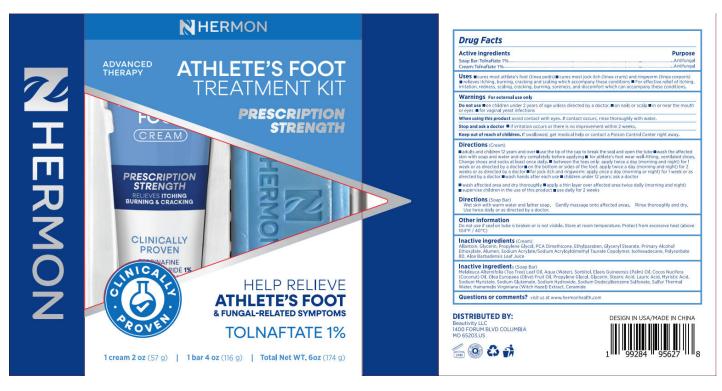
Cream:

Allantoin, Glycerin, Propylene Glycol, PCA Dimethicone, Ethylparaben, Glyc Ethoxylate, Alumen, Sodium Acrylate/Sodium Acryloyldimethyl Taurrate Copolymer, Isohexadecane, Polysorbate 80, Aloe Barbadensis Leaf Juice

Soap Bar:

Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aqua (Water), Sorlbitol, Elaeis Guineensis (Palm) Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Propylene Glycol, Glyceerin, Stearic Acid, Lauric Acid, Myristic Acid, Šodium Myristate, Sodium Glutamate, Sodium Hydroxide, Sodium Dodecylbenzene Sulfonate, Sulfur Thermal Water, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide

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HERMON ATHLETES FOOT TOLNAFTATE 1% KIT tolnaftate 1% kit kit Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:85398-018 Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:85398-018- 01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	10/31/2025	

Quant	Quantity of Parts		
Part #	Package Quantity	Total Product Quantity	
Part 1	0 CARTON	1 g in 116	
Part 2	1 TUBE	57 g	

Part 1 of 2

ATHLETE FOOT MEDICATED BAR

tolnaftate soap

Product Information	
Item Code (Source)	NDC:85398-007
Route of Administration	TOPICAL

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength
l	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1.16 g in 116 g

Inactive Ingredients		
Ingredient Name	Strength	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)		
GLYCERIN (UNII: PDC6A3C0OX)		
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)		
SULFUR (UNII: 70FD1KFU70)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0073W7L)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SODIUM GLUTAMATE (UNII: W81N5U6R6U)		
SODIUM MYRISTATE (UNII: 06BLC4V0IV)		
MYRISTIC ACID (UNII: 013V7S25AW)		
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)		
LAURIC ACID (UNII: 1160N9NU9U)		
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)		
SORBITOL (UNII: 506T60A25R)		

1	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:85398-007-	116 g in 1 CARTON; 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	10/31/2025		

Part 2 of 2

INITIAL DRUG LISTING - HERMON ATHLETES FOOT 1% TOLNAFTATE CREAM

tolnaftate 1% cream

Product Information		
Item Code (Source)	NDC:85398-017	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength
l	TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	0.57 g in 57 g

Inactive Ingredients				
Ingredient Name				
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)				
ALCOHOL (UNII: 3K9958V90M)				
POLYSORBATE 80 (UNII: 60ZP39ZG8H)				
ETHYLPARABEN (UNII: 14255EXE39)				
GLYCERYL STEARATE (UNII: 2300U9XXE4)				
DIMETHICONE 6 (UNII: RB8V8W9FQN)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ISOHEXADECANE (UNII: 918X1OUF1E)				
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)				
POTASSIUM ALUM (UNII: 1L24V9R23S)				
ALLANTOIN (UNII: 344S277G0Z)				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-017- 02	57 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	10/31/2025		

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raph Marketing Start Date	: Marketing End Date
10/31/2025	

Labeler - Beautivity LLC (096573788)

Registrant - Beautivity LLC (096573788)

Revised: 10/2025 Beautivity LLC