

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

Update-85398-018-01

- 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 accompany these conditions
- For effective relief of itching, irritation, 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 weeks.

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 the cap to break the seal and open the tube
- wash the affected 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 toes only: apply twice a day (morning and night) for 1 week or as directed by a doctor
- on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor
- for jock itch and ringworm: apply once a 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 for 2 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 Taurate Copolymer, Isohexadecane, Polysorbate 80, Aloe Barbadensis Leaf Juice

Soap Bar:

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 Thermal Water, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide

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Drug Facts	
Active ingredients	Purpose
Soap Bar: Tolnaftate 1%	Antifungal
Cream: Tolnaftate 1%	Antifungal
Uses ■ cures most athlete's foot (tinea pedis) ■ cures most jock itch (tinea cruris) and ringworm (tinea corporis) ■ relieves itching, burning, cracking and scaling which accompany these conditions ■ For effective relief of itching, irritation, redness, scaling, cracking, burning, soreness, and discomfort which can accompany these conditions.	
Warnings For external use only Do not use ■ 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 When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop and ask a doctor ■ if irritation occurs or there is no improvement within 2 weeks. Keep out of reach of children. 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 the cap to break the seal and open the tube ■ wash the affected 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 toes only: apply twice a day (morning and night) for 1 week, or as directed by a doctor. ■ on the bottom or sides of the foot: apply twice a day (morning and night) for 2 weeks or as directed by a doctor. ■ for jock itch and ringworm: apply once a 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 for 2 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.	
Other information 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)	
Inactive ingredients (Cream) Allantoin, Glycerin, Propylene Glycol, PCA Dimethicone, Ethylparaben, Glycerol Stearate, Primary Alcohol Ethoxylate, Alumen, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 80, Aloe Barbadensis Leaf Juice	
Inactive ingredients (Soap Bar) 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 Thermal Water, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide	
Questions or comments? visit us at www.hermonhealth.com	
DISTRIBUTED BY: Beautyity LLC 1400 FORUM BLVD COLUMBIA MO 65203.US	
DESIGN IN USA/MADE IN CHINA 	

HERMON ATHLETES FOOT TOLNAFTATE 1% KIT

tolnaftate 1% kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85398-018
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Packaging

Marketing Start Marketing End

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

Quantity of Parts

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

Part 1 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

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
DIMETHICONE 6 (UNII: RB8V8W9FQN)	
ALLANTOIN (UNII: 344S277G0Z)	
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)	

Packaging

Marketing Start	Marketing End
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#	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	

Part 2 of 2

ATHLETE FOOT MEDICATED BAR

tolnaftate soap

Product Information

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	1.16 g in 116 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM GLUTAMATE (UNII: W81N5U6R6U)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
SORBITOL (UNII: 506T60A25R)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
LAURIC ACID (UNII: 1160N9NU9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	
SULFUR (UNII: 70FD1KFU70)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-007-02	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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/31/2025	

Labeler - Beautivity LLC (096573788)**Registrant** - Beautivity LLC (096573788)

Revised: 3/2026

Beautivity LLC