ATHLETE FOOT TREATMENT KIT- terbinafine hydrochloride, tolnaftate
Beautivity LLC

Update-85398-008-01

Tolnaftate 1% (Soap Bar)

Terbinafine Hydrochloride 1% (Cream)

antifungal

Soap Bar
- 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.

Cream
- 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 external use only

- on children under 2 years of age unless directed by a doctor
- on nails and 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 use and ask a doctor
- If irritatioin occurs or there is no improvement within 2 weeks.

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

Soap Bar
- Wash the affected area thoroughly
- Allow Hermon Antifungal Soap to sit for 1-2 minutes before rinsing.
- Dry the area completely after washing.

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

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)

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

Inactive ingredients

Cream
Allantoin, Glycerin, Propylene Glycol, PCA Dimethicone, Ethylparaben, Glyceryl Stearate, Primary Alcohol Ethoxylate, Alumen, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexade- cane, Polysorbate 80, Aloe Barbadensis Leaf Juice, Parfum

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ATHLETE FOOT TREATMENT KIT

terbinafine hydrochloride, tolnaftate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:85398-008

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-008-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	08/20/2025	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 CARTON	60 g
Part 2	1 CARTON	232 g

Part 1 of 2

ATHLETE FOOT CREAM

terbinafine hydrochloride cream

Product Information	
Item Code (Source)	NDC:85398-006
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TERBINAFINE HYDROCHLORIDE (UNII: 012C11ZU6G) (TERBINAFINE - UNII:G7RIW8S0XP)	TERBINAFINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
POTASSIUM ALUM (UNII: 1L24V9R23S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
C12-15 PARETH-7 (UNII: 3XY03A79QH)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLPARABEN (UNII: 14255EXE39)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-006-01	60 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	08/18/2025	

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 g in 100 g

Inactive Ingredients

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

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		

Marketing Information

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

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/20/2025	

Labeler - Beautivity LLC (096573788)

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