

CLOTRIMAZOLE ANTIFUNGAL TREATMENT KIT- clotrimazole 1% Beautivity LLC

Initial Drug Listing - Clotrimazole antifungal treatment kit

Clotrimazole 1%

Antifungal

Proven clinically effective in the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis). For effective relief of itching, irritation, redness, scaling, cracking, burning, soreness, and discomfort which can accompany these conditions.

For external use only.

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

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

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

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

For cream

- 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.

For soap

- 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.

For cream:

Purified Water, White Petrolatum, Mineral Oil, Glycerol, Cetostearyl Alcohol, Glyceryl Mono-And Distearate, Dimethyl sulfoxide, Alcohol, Polyoxyethylene Lauryl Ether (Peregol 0), Edetate Disodium, Butylated Hydroxytoluene, Ethylparaben

For soap:

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

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

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Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)		CLOTRIMAZOLE	0.57 g in 57 g	
Inactive Ingredients				
Ingredient Name			Strength	
EDETATE DISODIUM (UNII: 7FLD91C86K)				
ETHYLPARABEN (UNII: 14255EXE39)				
WATER (UNII: 059QF0KO0R)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
GLYCEROL FORMAL (UNII: 3L7GR2604E)				
WHITE PETROLATUM (UNII: B6E5W8RQJ4)				
MINERAL OIL (UNII: T5L8T28FGP)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)				
ALCOHOL (UNII: 3K9958V90M)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-010-01	57 g in 1 BOTTLE; 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		08/31/2025	
Part 2 of 2				
HERMON CLOTRIMAZOLE ANTIFUNGAL SOAP. BAR				
clotrimazole 1% soap				
Product Information				
Item Code (Source)	NDC:85398-011			
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)			CLOTRIMAZOLE	1.16 g in 116 g
Inactive Ingredients				
Ingredient Name				Strength
MYRISTIC ACID (UNII: 0I3V7S25AW)				
SODIUM MYRISTATE (UNII: 06BLC4V0IV)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
LAURIC ACID (UNII: 1160N9NU9U)				
HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF WATER (UNII: 8FP93ED6H2)				
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)				
AQUA (UNII: 059QF0KO0R)				
SODIUM GLUTAMATE (UNII: W81N5U6R6U)				
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SORBITOL (UNII: 506T60A25R)				
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)				
GLYCERIN (UNII: PDC6A3C0OX)				
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)				
CERAMIDE 1 (UNII: 5THT33P7X7)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-011-01	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	08/31/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M005	08/31/2025	

Labeler - Beautivity LLC (096573788)

Registrant - Beautivity LLC (096573788)

