

TINEA VERSICOLOR TREATMENT BAR- clotrimazole soap

Beautivity LLC

Initial Drug Listing - Tinea Versicolor Treatment Bar

clotrimazole 1%

antifungal

Helps relieve and prevent itching, burning, cracking, and scaling associated with tinea versicolor infections.

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 or if 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.

- Wash the affected area thoroughly and allow the product to sit for 1-2 minutes before rinsing.
- Ensure the affected area is dried completely.
- Apply 1-2 times daily for 4 weeks.
- This product is not effective for use on the scalp or nails.

Melaleuca Alternifolia (Tea Tree) Leaf Oil, 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 Dodecylbenzenesulfonate, Sulfur, Hamamelis Virginiana Root Bark, Ceramide

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

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TINEA VERSICOLOR TREATMENT BAR

clotrimazole soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85398-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
LAURIC ACID (UNII: 1160N9NU9U)	

MYRISTIC ACID (UNII: 0I3V7S25AW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SULFUR (UNII: 70FD1KFU70)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
SODIUM GLUTAMATE (UNII: W81N5U6R6U)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-003-01	116 g in 1 CARTON; Type 0: Not a Combination Product	05/12/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	05/12/2025	

Labeler - Beautivity LLC (096573788)

Revised: 4/2025

Beautivity LLC