

**TINEA VERSICOLOR TREATMENT KIT- clotrimazole**  
**Beautivity LLC**

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**Update-85398-004-01**

Cream: Clotrimazole 1%  
Soap 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 & 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.

Cream: Purified Water, Camphor, Gentiana Lutea Root, Propylene Glycol, Glycerin, Methylparaben, Triethanolamine, Peppermint Oil

Soap Bar: 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 NP

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

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## TINEA VERSICOLOR TREATMENT KIT

clotrimazole kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85398-004
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-004-01	1 in 1 KIT; Type 0: Not a Combination Product	05/15/2025	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	60 g
Part 2	1 CARTON	116 g

### Part 1 of 2

# TINEA VERSICOLOR TREATMENT CREAM

clotrimazole cream

## Product Information

Item Code (Source) NDC:85398-002

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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
GENTIANA LUTEA ROOT (UNII: S72O3284MS)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
TROLAMINE (UNII: 9O3K93S3TK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85398-002-01	60 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	05/12/2025	

## Part 2 of 2

# TINEA VERSICOLOR TREATMENT BAR

clotrimazole soap

## Product Information

**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	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM GLUTAMATE (UNII: W81N5U6R6U)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	
CERAMIDE NP (UNII: 4370DF050B)	
SORBITOL (UNII: 506T60A25R)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0073W7L)	
WATER (UNII: 059QF0KOOR)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LAURIC ACID (UNII: 1160N9NU9U)	
SULFUR (UNII: 70FD1KFU70)	

## 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		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	05/15/2025	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug M005

05/15/2025

**Labeler** - Beautivity LLC (096573788)

Revised: 3/2026

Beautivity LLC