

KERACARE- menthol 1% gel
Avlon Industries, Inc.

KeraCare Dry & Itchy Scalp Glossifier

ACTIVE INGREDIENT

Menthol 1.00%

PURPOSE

Topical Analgesic

USE

for the temporary relief of itching associated with minor skin irritations of the scalp.

WARNINGS

for external use only

When using this product

avoid getting into eyes. In event of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

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

Directions

Adults: Apply to scalp at least twice per week. Use daily for maximum results. Children: Consult a physician.

INACTIVE INGREDIENTS

Petrolatum, Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil, Paraffin, Polyethylene, Salicylic Acid, Tocopheryl Acetate, Fragrance/Parfum, Olea Europaea (Olive) Fruit Oil, BHT, Sulfur, Alpha-Isomethyl Ionone, Amyl Cinnamal, Benzyl Salicylate, Eugenol, Geraniol, Hydroxycitronellal, Isoeugenol, Limonene, Linalool, Red

17/CI 26100.

KeraCare Glossifier

Product NDC 63766-001



KERACARE

Glossifier

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STYLE

Satisfaction Guaranteed Professional Formula



- Soothes an itchy scalp
- Instantly relieves itching
- Gentle enough for daily use
- Helps prevent the return of itchy scalp conditions.

Drug Facts	
Active Ingredient	Purpose
Menthol 1.00%	Topical Analgesic
Use for the temporary relief of itching associated with minor skin irritations of the scalp.	
Warnings	
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Drug Facts (Con't)
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■ condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.
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KERACARE

menthol 1% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63766-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

CASTOR OIL (UNII: D5340Y2I9G)
PARAFFIN (UNII: I9O0E3H2ZE)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
SALICYLIC ACID (UNII: O414PZ4LPZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SULFUR (UNII: 70FD1KFU70)
OLIVE OIL (UNII: 6UYK2W1W1E)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)
BENZYL SALICYLATE (UNII: WAO5MNMK9TU)
EUGENOL (UNII: 3T8H1794QW)
GERANIOL (UNII: L837108USY)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
ISOEUGENOL (UNII: 5M0MWW797U)
LIMONENE, (+/-)- (UNII: 9MC3I34447)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
D&C RED NO. 17 (UNII: ND733RX3JN)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63766-001-02	200 g in 1 CANISTER; Type 0: Not a Combination Product	04/06/2014	06/10/2027
2	NDC:63766-001-01	110 g in 1 CANISTER; Type 0: Not a Combination Product	04/06/2014	07/17/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/06/2014	07/17/2027

Labeler - Avlon Industries, Inc. (121278626)

Establishment

Name	Address	ID/FEI	Business Operations
Avlon Industries, Inc.		121278626	manufacture(63766-001)