

HAIR SANITY HAIR SANITY PART I- hydrocortisone acetate lotion/shampoo
Prime Enterprises Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hair Sanity Part I

Active Ingredients

Hydrocortisone acetate 0.5%

Purpose

Antipruritic (Anti-Itch)

Uses

- for the temporary relief of itching associated with minor skin irritations and rashes.

Warnings

For external use only.

Avoid contact with the eyes.

If conditions worsens or if symptoms persist, stop use of this product and consult a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply a quarter-sized amount to the top of the head and another quarter-sized amount to the sides of wet hair and scalp. Add additional water and cleanser for increased lather. Massage lather into scalp and rinse thoroughly with warm water. Use daily or minimum of 3 times per week.

Water, Sodium Lauroyl Methyl Isethionate, Acrylates Copolymer, Decyl Glucoside, Sodium Lauroamphoacetate, Sodium Methyl Cocoyl Taurate, Sodium Cocoyl Isethionate, Butylene Glycol, Glycereth-26, Cocamidopropyl Betaine, Fragrance, Glycerin, Glycol Stearate, Phenoxyethanol, Guar Hydroxypropyltrimonium Chloride, Sodium Hydroxide, Allantoin, BHT, Disodium EDTA, Ethylhexylglycerin, Caprylic/Capric Triglyceride, Methylpropanediol, 4-Terpineol, Isomalt, Rhododendron Ferrugineum Leaf Cell Culture Extract, Lecithin, Lactic Acid, Salicylic Acid, Sea Whip Extract, Salix Alba (Willow) Bark Extract

Hair Sanity Part I

Shampoo

HAIRSanity™

PART I of a two-part hair cleansing and conditioning system that will change the way you think about hair care.....forever.

8 FL OZ (237 mL)

HAIRSanity™ Shampoo

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Inactive ingredients	
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MADE IN U.S.A.

Manufactured for H Plus Holdings, Elkton, MD 21921
Customer Service: 800.422.0473



HSSH8072016
SHT8072016

HAIR SANITY HAIR SANITY PART I

hydrocortisone acetate lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0246
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
SODIUM LAUROYL METHYL ISETHIONATE (UNII: II6VCD3S6R)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
ALLANTOIN (UNII: 344S277G0Z)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERETH-26 (UNII: NNE56F2N14)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
ISOMALT (UNII: S870P55O2W)	
RHODODENDRON FERRUGINEUM LEAF (UNII: 30NOV1XI0P)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
4-TERPINEOL, (+)- (UNII: HZK34LN80N)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0246-4	237 mL in 1 TUBE; Type 0: Not a Combination Product	04/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0246) , manufacture(58443-0246) , label(58443-0246) , analysis(58443-0246)

Revised: 1/2020

Prime Enterprises Inc.