

HAIRSANITY STEP 1- hydrocortisone acetate shampoo

H Plus Holdings

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.

HairSanity™ Step 1

Drug Facts

Active ingredient

Hydrocortisone acetate 0.5%

Purpose

Antipruritic

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 condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and do not begin use of any other hydrocortisone product unless you have consulted 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. Children under 2 years of age: do not use, consult a doctor. Store at room temperature.

Inactive ingredients

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, Menthol, Benzyl Alcohol, Isopropyl Palmitate, Polyglyceryl-4 Laurate, Poloxamer 407, Citric Acid

PRINCIPAL DISPLAY PANEL - 89 mL Tube Label

**HAIR
SANITY™
STEP 1**

REGULAR USE OF
OUR **2 STEP SYSTEM**
WILL CHANGE THE
WAY YOUR HAIR
LOOKS AND FEELS
FOREVER.

ANTI-ITCH SHAMPOO

for beautiful, more manageable,
and softer hair.

Hydrocortisone Acetate

3 FL OZ (89 mL)

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MADE IN U.S.A.

Manufactured for H Plus Holdings, LLC,
109 N Bridge Street, Elkton, MD 21921

Customer Service: 800.422.0473

HSSH302017

12M SHL3072017

HAIRSANITY STEP 1

hydrocortisone acetate shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71605-000
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
SODIUM LAUROYL METHYL ISETHIONATE (UNII: II6VCD3S6R)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERETH-26 (UNII: NNE56F2N14)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
ALLANTOIN (UNII: 344S277G0Z)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
4-TERPINEOL, (+)- (UNII: HZK34LN80N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
ISOMALT (UNII: S870P55O2W)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H10UX5)	
SALIX ALBA BARK (UNII: 205MXS71H7)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
RHODODENDRON FERRUGINEUM LEAF (UNII: 30NOV1XI0P)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71605-000-01	237 mL in 1 TUBE; Type 0: Not a Combination Product	08/10/2017	
2	NDC:71605-000-04	89 mL in 1 TUBE; Type 0: Not a Combination Product	08/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	08/10/2017	

Labeler - H Plus Holdings (080731249)

Revised: 7/2017

H Plus Holdings