

H PLUS HOLDINGS NOURISHING- hydrocortisone acetate shampoo Prime Enterprises

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.

H Plus 1.0% Hydrocortisone Nourishing Shampoo 3 Fl. Oz.

Active Ingredients

Hydrocortisone acetate 1%

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 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.

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

Directions

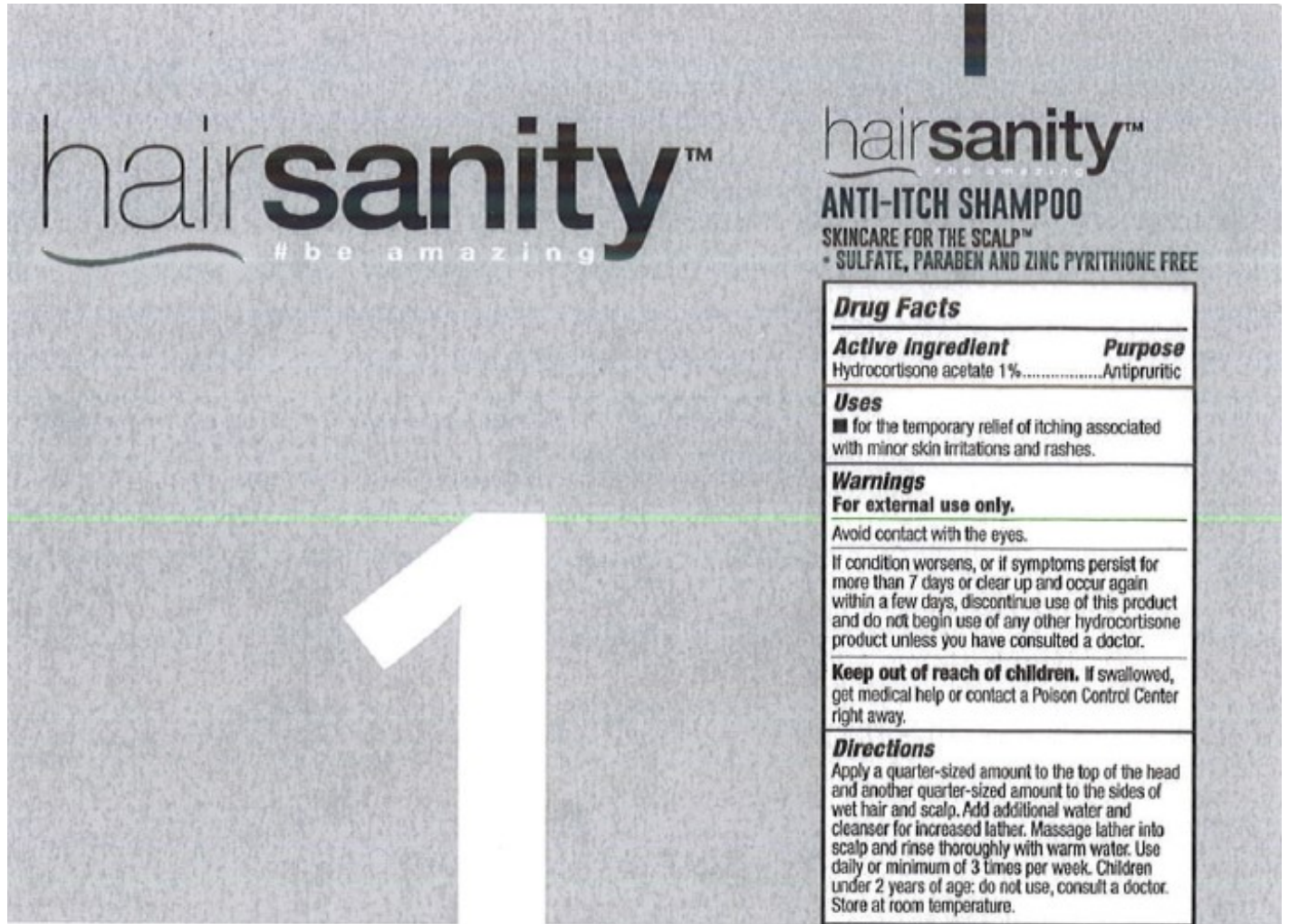
Apply a quarter-sized amount to the top of the head and another quarter-sized amount to the sides of wet hair and scalp. Add additional water and cleanser for increased lather. Massage lather into scalp and rinse thoroughly with warm water. Use daily or minimum of 3 times per week. Children under 2 years of age: do not use, consult a doctor. Store at room temperature.

Inactive Ingredients

4-Terpineol, Acrylates Copolymer, Allantoin, Benzyl Alcohol, BHT, Butylene Glycol, Caprylic/Capric Triglyceride, Citric Acid, Cocamidopropyl Betaine, Decyl Glucoside,

Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceth-26, Glycerin, Glycol Stearate, Guar Hydroxypropyltrimonium Chloride, Isomalt, Isopropyl Palmitate, Lactic Acid, Lecithin, Menthol, Methylpropanediol, Phenoxyethanol, Poloxamer 407, Polyglyceryl-4 Laurate, Rhododendron Ferrugineum Leaf Cell Culture Extract, Salicylic Acid, Salix Alba (Willow) Bark Extract, Sea Whip Extract, Sodium Cocoyl Isethionate, Sodium Hydroxide, Sodium Lauroamphoacetate, Sodium Lauroyl Methyl Isethionate, Sodium Methyl Cocoyl Taurate, Water

Hair Sanity Anti-Itch Shampoo Step 1 - 3 Fl. Oz.



**STEP 1
ANTI-ITCH
SHAMPOO**

Look In The Mirror.
It Would Be Insane To Go Back.
HYDROCORTISONE ACETATE



3 FL OZ (89 mL)

hair **sanity**[™]

ANTI-ITCH SHAMPOO

SKINCARE FOR THE SCALP[™]

- SULFATE, PARABEN AND ZINC PYRITHIONE FREE

Drug Facts

Active Ingredient	Purpose
Hydrocortisone acetate 1%	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, Sodium Cocoyl Isethionate, Decyl Glucoside, Butylene Glycol, Glyceth-26, Sodium Lauroamphoacetate, Sodium Methyl Cocoyl Taurate, 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

**MADE IN U.S.A.
FROM U.S. AND IMPORTED INGREDIENTS**

Manufactured for HSP Technologies, LLC HSSH3-519
200 S Bridge Street, Elkton, MD 21921
Customer Service: 800.422.0473

H PLUS HOLDINGS NOURISHING

hydrocortisone acetate shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0412
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WILLOW BARK (UNII: S883J9JDYX)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERETH-26 (UNII: NNE56F2N14)	
GLYCERIN (UNII: PDC6A3C0OX)	
RHODODENDRON FERRUGINEUM LEAF (UNII: 30NOV1XI0P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)	
ALLANTOIN (UNII: 344S277G0Z)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
SODIUM LAUROYL METHYL ISETHIONATE (UNII: II6VCD3S6R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
LACTIC ACID (UNII: 33X04XA5AT)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	

ISOMALT (UNII: S870P55O2W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Product Characteristics

Color	white (White Pearl)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0412-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	06/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/12/2019	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(58443-0412) , label(58443-0412) , analysis(58443-0412) , pack(58443-0412)

Revised: 10/2021

Prime Enterprises