H PLUS HOLDINGS NOURISHING- salicylic acid rinse 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 1.85% Salicylic Acid Anti-Dandruff Conditioner 8 Fl. Oz.

Active Ingredients

Salicylic Acid 1.85%

Purpose

Anti-Dandruff

Uses

helps prevent reoccurance of flaking and itching associated with dandruff.

Warnings

For external use only.

Avoid contact wih the eyes. If contact occurs, rinse eyes thoroughly with water.

If condition worsens, or does not improve after regular use of this product as directed, stop use of this product and consult a doctor.

Keep out of reach of children.

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

Directions

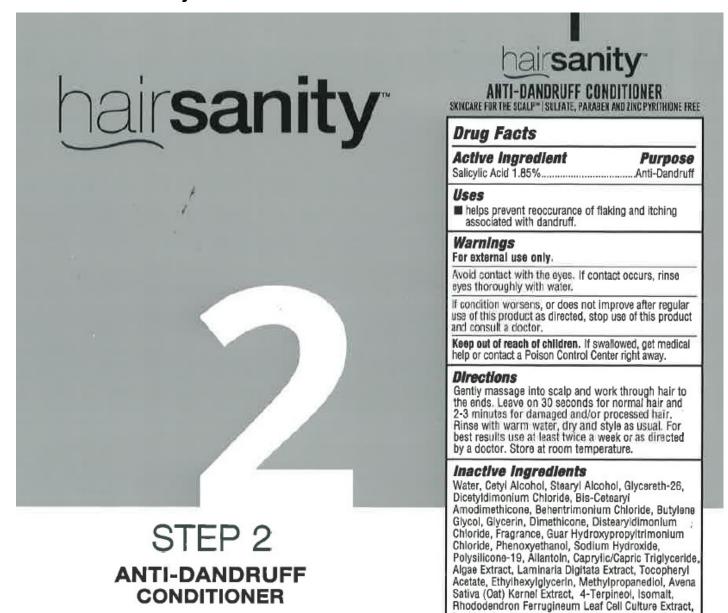
Gently massage into scalp and work through hair to the ends. Leave on 30 seconds for normal hair and 2-3 minutes for damaged and/or processed hair. Rinse with warm water, dry and style as usual. For best results use at least twice a week or as directed by a doctor. Store at room temperature.

Inactive Ingredients

Water, Cetyl Alcohol, Stearyl Alcohol, Glycereth-26, Bis-Cetearyl Amodimethicone, Dicetyldimonium Chloride, Behentrimonium Chloride, Butylene Glycol, Glycerin, Dimethicone, Distearyldimonium Chloride, Fragrance, Guar Hydroxypropyltrimonium

Chloride, Phenoxyethanol, Isopropyl Alcohol, Sodium Hydroxide, Alcohol Denat., Caprylic/Capric Triglyceride, Tocopheryl Acetate, Allantoin, Dipropylene Glycol, Polysilicone-19, Ethylhexylglycerin, Methylpropanediol, Avena Sativa (Oat) Kernel Extract, 4-Terpineol, Lecithin, Isopropyl Palmitate, Poloxamer 407, Isomalt, Algae Extract, Salix Alba (Willow) Bark Extract, Sea Whip Extract, Polyglyceryl-4 Laurate, Menthol, Benzyl Alcohol, Laminaria Digitata Extract, Rhododendron Ferrugineum Leaf Cell Culture Extract

H Plus 1.85% Salicylic Acid Anti-Dandruff Conditioner 8 Fl. Oz.



SALICYLIC ACID



MADE IN U.S.A. FROM U.S. AND IMPORTED INGREDIENTS
Manufactured for Hair Sense Holdings, LLC
16361 NW 49th Avenue, Miaml, Florida 33014

Lecithin, Lactic Acid, Sea Whip Extract, Salix Alba

(Willow) Bark Extract



salicylic acid rinse

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Product Type HUMAN OTC DRUG Item Code (So	rce) NDC:58443-0249
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Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII: O414PZ4LPZ)	SALICYLIC ACID	17.575 mg in 1 mL

Ingredient Name	Strengtl
DICETYLDIMONIUM CHLORIDE (UNII: 6F4SX2007N)	
ISOMALT (UNII: S870P5502W)	
ALCOHOL (UNII: 3K9958V90M)	
BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
OAT (UNII: Z6J799EAJK)	
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WILLOW BARK (UNII: S883J9JDYX)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERETH-26 (UNII: NNE56F2N14)	
GLYCERIN (UNII: PDC6A3C0OX)	
RHODODENDRON FERRUGINEUM LEAF (UNII: 30NOV1XI0P)	
4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)	
ALLANTOIN (UNII: 344S277G0Z)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNI B16G315W7A)	II:
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	

DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)

Product Characteristics		
Color	white	Score
Shape		Size
Flavor		Imprint Code
Contains		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:58443-0249-4	237 mL in 1 TUBE; Type 0: Not a Combination Product	06/13/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/13/2019	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment				
Name	Address	ID/FEI	Business Operations	
Prime Enterprises		101946028	manufacture(58443-0249) , label(58443-0249) , analysis(58443-0249) , pack(58443-0249)	

Revised: 10/2021 Prime Enterprises