HAND AND WRIST PAIN CREAM- histamine dihydrochloride cream
Sombra Cosmetics, 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.

Hand and Wrist Pain Cream

Active Ingredients

Histamine Dihydrochloride 0.025%

Keep out of reach of children

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

PURPOSE

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Topical Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains and bruises

Warnings

For external use only. **Do not use** on wounds or damaged skin or if you are allergic to ingredients in this product. **When using this product**: avoid contact with eyes. If product gets into eyes, rinse thoroughly with water. Do not bandage tightly or use a heating pad.

Stop use and ask doctor if: rash appears. Condition worsens. If symptoms persist for more than 7 days or if symptoms clear up and occur again within a few days.

If pregnant or breast feeding, ask a health professional before use.

Directions

For Use by Adults and Children over 12 years. Apply a thin layer to pain site and massage until thoroughly absorbed into skin. Apply no more than 3 to 4 times daily.

Children 12 years or younger consult a physician

Inactive Ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel), Aqua (Purified Water), Ascorbic Acid (Vitamin C), Butylene Glycol, Camellia Sinensis (Green Tea) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Emu Oil, Ethylhexylglycerin, Ethylhexyl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Seed Oil, C13-14 Isoparaffin, Laureth-7, Magnesium Sulfate, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Potassium Sorbate, Purica Granatum (Pomegranate) Extract, Saccharide Isomerate, Sodium Polyacrylate, Tochopheryl Acetate (Vitamin E), Trideceth-6, Vaccinium Angustifolium (Blueberry) Fruit Extract, Zemea (Corn) Propanediol

Questions or Comments?

Call 1-888-600-4642

Label

HAND AND WRIST PAIN CREAM

histamine dihydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61577-8122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	.00025 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Water (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
EMU OIL (UNII: 344821WD61)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PUNICA GRANATUM SEED (UNII: 7294Z34NS7)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
VACCINIUM ANGUSTIFOLIUM WHOLE (UNII: R3538BZ1BW)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61577-8122-4	119 g in 1 TUBE; Type 0: Not a Combination Product	12/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/09/2019	

Labeler - Sombra Cosmetics, Inc. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics, Inc.		097464309	manufacture(61577-8122) , label(61577-8122)

Revised: 12/2019 Sombra Cosmetics, Inc.