

ARTHRITIS PAIN RELIEF CREAM- histamine dihydrochloride cream
Sombra Cosmetics Inc.

Australian Dream Arthritis Cream

Active Ingredients

Histamine Dihydrochloride .025%

Purpose

External Analgesic

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

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backaches, strains & bruises.

Warnings

For external use only. Do not use on wounds or damaged skin or if you are allergic to ingredients in the 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.

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

Aqua (Purified Water), Butylene Glycol, Emu Oil, Ethylhexylglycerin, Ethylhexyl Stearate, Helianthus

Annuus (Sunflower) Seed Oil, C13-14 Isoparaffin, Laureth-7, Methylsulfonylmethane (MSM),

Polyacrylamide, Potassium Sorbate, Sodium Polyacrylate, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Trideceth-6, Chondroitin Sulfate, Glucosamine Sulfate

Questions or Comments

Call 1-888-600-4642

Dosage and Administration

Apply no more than 3 to 4 times daily.

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Indications and Usage Section

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AD Arthritis 9oz Carton



ARTHRTIS PAIN RELIEF CREAM

histamine dihydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-8120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.00025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POTASSIUM SORBATE (UNII: 1VPU26JZ Z 4)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED (UNII: R9N3379M4Z)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)
TETRASODIUM EDTA (UNII: MP1J8420LU)
SODIUM CARBONATE (UNII: 45P3261C7T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
LAURETH-7 (UNII: Z95S6G8201)
EMU OIL (UNII: 344821WD61)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM CHONDROITIN SULFATE (PORCINE; 5500 MW) (UNII: H5BJH23Z9A)
WATER (UNII: 059QF0KO0R)
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-8120-5	1 in 1 CARTON	10/23/2024	
1	NDC:61577-8120-4	119 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:61577-8120-8	1 in 1 CARTON	10/23/2024	
2	NDC:61577-8120-9	266 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:61577-8120-1	1 in 1 CARTON	10/23/2024	
3	NDC:61577-8120-2	59 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/23/2024	

Labeler - Sombra Cosmetics Inc. (097464309)

Establishment			
Name	Address	ID/FEI	Business Operations
Sombra Cosmetics Inc.		097464309	manufacture(61577-8120) , label(61577-8120)