AUSTRALIAN DREAM BACK PAIN- histamine dihydrochloride cream
Sombra Cosmetics, Inc.

Australian Dream Back Pain Cream

Active Ingredients

Histamine Dihydrochloride 0.05%

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 simple backache

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

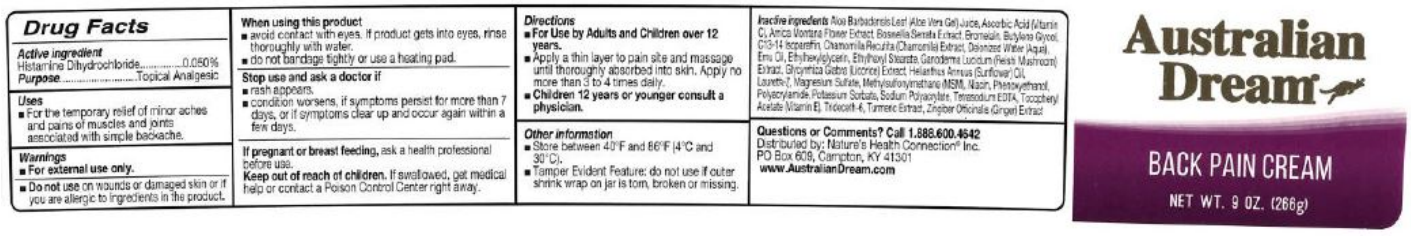
Aloe Barbadensis Leaf (Aloe Vera Gel), Aqua (Purified Water), Ascorbic Acid (Vitamin C), Arnica Montana Flower Extract, Boswellia Serrata Extract, Bromelain, Butylene Glycol,

Chamomilla Recutita (Chamomile) Extract, Emu Oil, Ethylhexylglycerin, Ethylhexyl Stearate, Ganoderma Lucidum (Reishi Mushroom) Extract, Glycyrrhiza Glabra (Licorice) Extract, Helianthus Annuus (Sunflower) Seed Oil, C13-14 Isoparaffin, Laureth-7, Magnesium Sulfate, Methylsulfonylmethane (MSM), Niacin, Phenoxyethanol, Polyacrylamide, Potassium Sorbate, Sodium Polyacrylate, Tetrasodium EDTA, Tochopheryl Acetate (Vitamin E), Trideceth-6, Turmeric Extract, Zingiber Officinalis (Ginger) Extract

Questions or Comments?

Call 1-888-600-4642

Label



AUSTRALIAN DREAM BACK PAIN

histamine dihydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61577-8121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	.0005 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
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)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
LAURETH-7 (UNII: Z95S6G8201)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TURMERIC (UNII: 856YO1Z64F)	
GINGER (UNII: C5529G5JPQ)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GANODERMA LUCIDUM WHOLE (UNII: J5P04QW0CF)	
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	
BROMELAINS (UNII: U182GP2CF3)	
NIACIN (UNII: 2679MF687A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-8121-9	266 g in 1 JAR; Type 0: Not a Combination Product	01/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	01/18/2024	

Labeler - Sombra Cosmetics, Inc. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics, Inc.		097464309	manufacture(61577-8121) , label(61577-8121)

Revised: 1/2024 Sombra Cosmetics, Inc.