

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

Australian Dream Back Pain Cream

Active Ingredients

Histamine Dihydrochloride .025%

Purpose

Topical Analgesic

Keep out of reach of children

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

Uses

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

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.

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, Tocopheryl Acetate (Vitamin E), Trideceth-6, Turmeric Extract, Zingiber Officinalis (Ginger) Extract

Questions or Comments

Call 1-888-600-4642

Dosage and Administration

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Indications & Usage Section

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AD 2 oz Back Pain Cream Box

DIE LINE DOES NOT PRINT



File	AUD-403 2 oz Back Pain Cream Box.1 FA.PAI	Date	9/29/2023
Cust	Nature's Health Connection	Agency	Creative Spot
Job	AUD-403 2 oz Back Pain Cream Box	Ag Contact	Mitch Greenwald
Desc	2 oz Arthritis Cream Box	Phone	614-280-9280
Size	XX	Designer	Chris Rankin
Paper	24 pt. C1S		
Details:	4 Spot Color (PMS 249, PMS 262, PMS 123, Black), Flood Varnish or Spot UV.		



PINK represents the SPOT UV coating. DO NOT PRINT AS PINK.



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 -	HISTAMINE	0.0005 g

UNII:820484N813)

DIHYDROCHLORIDE

in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GANODERMA LUCIDUM WHOLE (UNII: J5P04QW0CF)	
TETRASODIUM EDTA (UNII: MP1J8420LU)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GINGER (UNII: C5529G5JPQ)	
EMU OIL (UNII: 344821WD61)	
LAURETH-7 (UNII: Z95S6G8201)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED (UNII: R9N3379M4Z)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	
GLYCYRRHIZA GLABRA (LICORICE) ROOT (UNII: 2788Z9758H)	
BROMELAINS (UNII: U182GP2CF3)	
NIACIN (UNII: 2679MF687A)	
TURMERIC (UNII: 856YO1Z64F)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
ALOE BARBADENSIS LEAF (UNII: ZY81Z83H0X)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
CHAMOMILE (UNII: FGL3685T2X)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-8121-3	1 in 1 CARTON	09/29/2023	
1	NDC:61577-8121-2	59 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:61577-8121-5	1 in 1 CARTON	02/20/2026	
2	NDC:61577-8121-4	119 g in 1 JAR; Type 0: Not a Combination Product		
3	NDC:61577-8121-8	1 in 1 CARTON	01/18/2024	
3	NDC:61577-8121-9	266 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	09/29/2023	

Labeler - Sombra Cosmetics Inc. (097464309)

Establishment

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

Revised: 5/2026

Sombra Cosmetics Inc.