

**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.*

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**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**

PURPOSE

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 Barbadosensis 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, TochoIPHERYL Acetate (Vitamin E), Trideceth-6, Vaccinium Angustifolium (Blueberry) Fruit Extract, Zemea (Corn) Propanediol

Questions or Comments?

Call 1-888-600-4642

Label



Empty Tube Guarantee  
Relieves Repetitive Motion Pain  
Trusted Relief  
Real Medicine

Australian Dream  
Real Medicine Trusted Relief

Australian Dream  
Real Medicine Trusted Relief

**Drug Facts (continued)**

**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.

**Other information**

- Store between 40°F and 86°F (4°C and 30°C).
- Tamper Evident Feature: do not use if seal under cap is torn, broken or missing.

**Inactive ingredients**

Aloe Barbadosensis Leaf (Aloe Vera Gel) Juice, 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, C15-14 Isoparaffin, Laureth-7, Magnesium Sulfate, Methylcellulose/methane (MSM), Phenoxysulfonate, Polyacrylamide, Potassium Sorbate, Punica Granatum (Pomegranate) Extract, Purified Water (Aqua), Saccharide Isomerate, Sodium Polyacrylate, Tocopheryl Acetate (Vitamin E), Trideceth-6, Vaccinium Angustifolium (Blueberry) Fruit Extract, Zinnia (Cotton) Propanediol

**Questions or Comments?**

Call 1.888.600.4642  
Distributed by:  
Nature's Health Connection® Inc.  
PO Box 606, Campton, KY 41301  
[www.AustralianDream.com](http://www.AustralianDream.com)

Australian Dream  
Real Medicine Trusted Relief

Australian Dream® temporarily relieves minor aches, pain and discomfort.

- Hand & Wrist Pain
- Repetitive Motion Pain
- Frequent Aches in Fingers and Joints

Australian Dream® moisturizes as it effectively relieves pain.

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Australian Dream

Active Ingredient  
Histamine Dihydrochloride

Hand & Wrist Pain Cream

ODOR FREE  
BURN FREE  
NON-GREASY  
NON-STAINING

100% Money Back Guarantee

NET WT. 2 OZ. (59g)

**Drug Facts**

Active ingredient	Purpose
Histamine Dihydrochloride	Topical Anesthetic
0.025%	

**Uses**

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

**Warnings**

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**Stop use and ask a 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 breastfeeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

KOSKA OFFICE



histamine dihydrochloride cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-8122
<b>Route of Administration</b>	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: 059QF0K00R)	
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.