**ARTHRITIS PAIN RELIEF 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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**Arthritis Pain Relief 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

**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

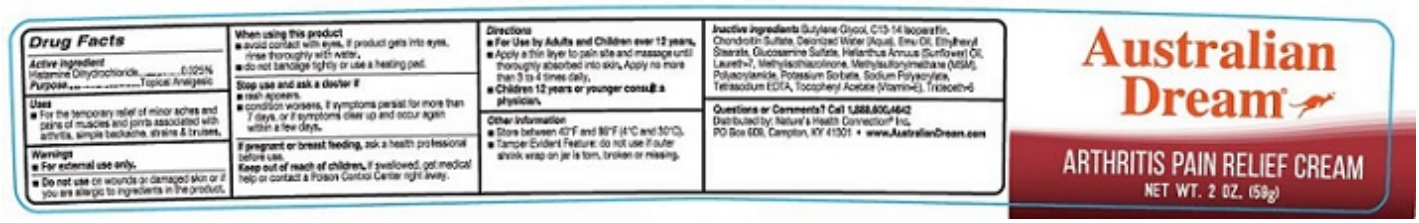
**Inactive Ingredients**

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, Tochopheryl Acetate (Vitamin E), Trideceth-6, Chondroitin Sulfate, Glucosamine Sulfate

**Questions or Comments?**

Call 1-888-600-4642

## Label




# ARTHRITIS 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 | .00025 g in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BUTYLENE GLYCOL** (UNII: 3XUS85K0RA) | |
| **EMU OIL** (UNII: 344821WD61) | |
| **ETHYLHEXYL STEARATE** (UNII: EG3PA2K3K5) | |
| **SUNFLOWER OIL** (UNII: 3W1JG795YI) | |
| **C13-14 ISOPARAFFIN** (UNII: E4F12ROE70) | |
| **LAURETH-7** (UNII: Z95S6G8201) | |
| **GLUCOSAMINE SULFATE** (UNII: 1FW7WLR731) | |
| **DIMETHYL SULFONE** (UNII: 9H4PO4Z4FT) | |
| **EDETATE SODIUM TETRAHYDRATE** (UNII: L13NHD21X6) | |
| **METHYLISOTHIAZOLINONE** (UNII: 229D0E1QFA) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM POLYACRYLATE (8000 MW)** (UNII: 285CYO341L) | |
| **TOCOPHEROL** (UNII: R0ZB2556P8) | |
| **TRIDECETH-6** (UNII: 3T5PCR2H0C) | |
| **CHONDROITIN SULFATE (BOVINE)** (UNII: 6IC1M3OG5Z) | |
| **POLYACRYLAMIDE (10000 MW)** (UNII: E2KR9C9V2I) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |

| | | | | |
|---|---|---|---|---|
| **1** | NDC:61577-8120-4 | 119 g in 1 JAR; Type 0: Not a Combination Product | 12/10/2019 | |
| **2** | NDC:61577-8120-2 | 59 g in 1 JAR; Type 0: Not a Combination Product | 12/10/2019 | |
| **3** | NDC:61577-8120-3 | 59 g in 1 TUBE; Type 0: Not a Combination Product | 12/10/2019 | |
| **4** | NDC:61577-8120-9 | 266 g in 1 JAR; 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(61577-8120) , label(61577-8120) |

Revised: 12/2019 Sombra Cosmetics, Inc.