

**AUSTRALIAN DREAM POWER 4 MUSCLE AND JOINT PAIN RELIEF CREAM-
camphor, menthol, capsacin, methyl salicylate 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.

Australian Dream Power 4 Muscle & Joint Pain Relief Cream

Active Ingredients

Camphor 3%, Capsaicin 0.025%, Methyl Salicylate 10%, Menthol 3%

Keep out of reach of children and pets.

If swallowed, get medical help or contact a Poison Control Center right away

PURPOSE

Topical Analgesic

Uses

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

Warnings

For external use only. Allergy Alert: If prone to allergic reaction from aspirin or salicylates, capsicum or chili peppers, or any ingredients in this product, consult a doctor before use. Do not use on wounds or damaged, broken, or irritated skin, at the same time as other topical analgesics. **When using this product,** use only as directed. **Read and follow all directions and warning on this label.** Avoid contact with eyes and mucous membranes. If contact is made, rinse thoroughly with water. Rare cases of serious burns have been reported with this type of product. Avoid applying into skin folds. Discontinue use at least 1 hour before a bath, shower, swim, or sweating. Do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use. A transient burning sensation may occur upon application but generally disappears in several days. If severe burning sensation occurs, discontinue use immediately. Do not expose the area treated with product to heat or direct sunlight. **Stop use and ask a doctor if,** rash, redness or irritation appears, condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days. **If pregnant or breast-feeding,** ask a health care professional before use.

Directions

For use by adults 18 years of age and older. Apply a thin layer to affected area not more than 3 to 4 times daily. Wash hands with soap or dishwashing liquid after application. If using on hands, allow 30 minutes for absorption before washing hands. Massage into painful area until thoroughly absorbed into skin. **Children under 18 years consult a physician.** Store between 40F and 86F (4C and 30C), Tamper Evident Feature: do not use if outer shrink wrap on jar is torn, broken or missing.

Inactive Ingredients

Aloe Barbadensis (Aloe Vera) Leaf Juice, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Emu Oil, Glycerin, Phenoxyethanol, Polysorbate 60, Purified Water, Sodium Carbonate, Stearic Acid, Tocopheryl Acetate, Yucca Schidigera Root Extract.

Questions or Comments?

Call 1-888-600-4642

Drug Facts Active Ingredients Camphor 3% Capsaicin 0.025% Methyl Salicylate 15% Menthol 3% Purpose External Analgesic External Analgesic External Analgesic External Analgesic Uses For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple bursitis, strains, sprains, and tendinitis. Warnings For external use only. Allergy Alert: If prone to allergic reaction from aspirin or salicylates, capsaicin or chili peppers, or any ingredient in this product, consult a doctor before use.	Do not use on wounds or damaged, broken, or irritated skin. at the same time as other topical analgesics. When using this product use only as directed. Read and follow all directions and warnings on this label. avoid contact with eyes and mucous membranes. If contact is made, rinse thoroughly with water. rare cases of serious burns have been reported with products of this type. avoid applying into skin folds. discontinue use at least 1 hour before a bath, shower, swim, or sweating. do not burnage tightly or apply heated heat (such as heating pads) or a medicated patch to the area of use.	Directions For use by adults 18 years of age and older. Apply a thin layer to affected area not more than 3 to 4 times daily. Wash hands with water and soap or dishwashing liquid after application. If using on hands, allow 30 minutes for absorption before washing hands. Massage into painful area until thoroughly absorbed into skin. Children under 18 years consult a physician. Other information Store between 40°F and 86°F (4°C and 30°C). Tamper Evident Feature: do not use if outer shrink wrap on jar is torn, broken or missing.	Inactive Ingredients Aloe Barbadensis (Aloe Vera) Leaf Juice, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Emu Oil, Glycerin, Phenoxyethanol, Polysorbate 60, Purified Water, Sodium Carbonate, Stearic Acid, Tocopheryl Acetate, Yucca Schidigera Root Extract. Questions or Comments? Call 1.888.600.4642 Distributed by: Nature's Health Connection® Inc. PO Box 808, Campton, KY 41301 www.AustralianDream.com	Australian Dream POWER 4 MUSCLE & JOINT PAIN RELIEF CREAM NET WT. 4 OZ. (119g)
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AUSTRALIAN DREAM POWER 4 MUSCLE AND JOINT PAIN RELIEF CREAM

camphor, menthol, capsaicin, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-8220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.10 g in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPBOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPBOR (SYNTHETIC)	0.03 g in 1 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EMU OIL (UNII: 344821WD61)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM CARBONATE (UNII: 45P3261C7T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-8220-4	119 g in 1 JAR; Type 0: Not a Combination Product	05/10/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/10/2023	

Labeler - Sombra Cosmetics, Inc. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics, Inc.		097464309	manufacture(61577-8220) , label(61577-8220)

Revised: 5/2023

Sombra Cosmetics, Inc.