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. Allery Alert: If prone to allergic reaction from asprin or salicylates, capsisum 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. Aviod 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 leat 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 notexpoes the area treated with product to heat or direct sunlight. Stop use and ask a doctor if, rash, redness or irritation appears, condition worsens, symtoms 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

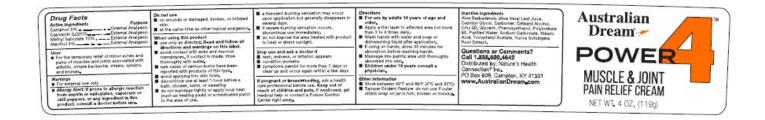
For use by adults 18 years of age and older. Apply a thin layer to affected area not more than 3 to 4 times daily. Wash hands with soap or dishwashing liquid after application. If using on hands, allow 30 minutes for absorption before washing hands. Massage intopainful area until thoroughly absorbed 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, Purifed Water, Sodium Carbonate, Stearic Acid, Tocopheryl Acetate, Yucca Schidigera Root Extract.

Questions or Comments?

Call 1-888-600-4642



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camphor, menthol, capsacin, 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	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.03 g in 1 g	
CAPSAICIN (UNII: S07044R1ZM) (CAPSAICIN - UNII:S07044R1ZM)	CAPSAICIN	0.025 g in 1 g	

Inactive Ingredients			
Strength			
TOCOPHEROL (UNII: R0ZB2556P8)			
POLYSORBATE 60 (UNII: CAL22UVI4M)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
EMU OIL (UNII: 344821WD61)			
GLYCERIN (UNII: PDC6A3C0OX)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)			

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.