DEEP CORE PAIN RELIEVING GEL WARM THERAPY- menthol camphor gel
SOMBRA COSMETICS INC.

Deep Core Pain Relief Gel Warm Therapy

Active Ingredients

Menthol USP 3%, Camphor 3%, Capsaicin 0.025%

Purpose

Purpose
External Analgesic

Keep out of reach of children

Keep out of reach of children

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: arthritis, simple backaches, arthritis, sprains, strains, and bruises.

Warnings

For external use only. Do not use on wounds, damaged, broken, or irritated skin. Do not bandage tightly or apply heating pads or medicated patch to the area of use. If pregnant or breast feedong, ask a healthcare professional before use. Keep out of reach of children and pets.

Directions

Adults 18 years and above: Apply thin layer to the affected area not more than 3-4 times daily. Massage until cream absorbs into skin. Wash hands with water and soap after application. **Adults and children 2 - 18 years** of age consult a doctor before use. **Children aged under 2, do not use.**

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Arnica Montana Extract, Camellia Sinensis Leaf Extract, Carbomer, Citrus Aurantium Dulcis (orange) Peel Oil, Citrus Grandis (Grapefruit) Fruit Extract, Decyl Glucoside, Dimethyl Isosorbide, Ethylhexylglycerin, Glucosamine Sulfate, Glycerin, Methylsulfonylmethane (MSM), Phenoxyethanol, Polysorbate 20, Purified Water, Pyridoxine Hydrochloride (Vitamin B6), Sodium Carbonate, Tocopheryl Acetate, Vernonia Amygdalina (Bitter Leaf) Extract, Witch Hazel Extract.

Questions or Comments

505-492-4611

DEEP CORE PAIN RELIEVING GEL WARM THERAPY

menthol camphor gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61577-2800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	.03 g in 0.03 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.03 g in 0.03 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
ALOE AFRICANA LEAF (UNII: S937Y6JPCZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	
CAPSAICIN (UNII: S07O44R1ZM)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
VERNONIA APPENDICULATA LEAF (UNII: 4SO50QHC3B)	
ORANGE PEEL (UNII: TI9T76XD44)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM CARBONATE (UNII: 45P3261C7T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-2800-1	85.05 g in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	03/01/2024	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-2800) , label(61577-2800)

Revised: 3/2024 SOMBRA COSMETICS INC.