

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 feeding, 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



Pain Relief Gel

Warm Therapy

with:
Arnica, Vit.B6
Capsaicin

NET 3oz / 85.05 g

Arthritis, Back + Knee Pain

Drug Facts	NDC 61577-2800-1
Active Ingredients	Purpose
Menthol, USP 3.0%	External analgesic
Camphor, USP 3.0%	External analgesic
Capsaicin 0.025%	External analgesic
Uses: Temporarily relieves minor aches and pains of muscles and joints associated with: arthritis, simple backache, sprains, strains, and bruises. Can be used on Back, Neck, Knee, Hand, Foot.	
Warnings: FOR EXTERNAL USE ONLY. *Do not use on wounds or damaged skin. *If pregnant or breast feeding ask a healthcare professional before use. Do not use with external heat. When using this product: *Avoid bandaging tightly. *Avoid contact with eyes. If contact is made rinse thoroughly with clean room temperature water. *Keep out of reach of children. Wash hands with water and soap after use.	
Stop use and ask a doctor if: *Condition worsens. *Symptoms persist for more than 7 days. *Rash, redness, or irritation appears. *Symptoms clear up and re-occur again within a few days.	
Directions: Adults and children 18 years of age and older: Apply gel onto the affected areas not more than 3-4 times daily. *Rub in thoroughly with finger tips (if needed) until gel is absorbed. * Children under 18 years: ask a doctor before use. This product is not intended to diagnose, treat, cure, nor prevent any disease.	
Inactive Ingredients: Aloe Barbadosensis 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, Hamamelis Virginiana (Witch Hazel) Extract, Phenoxyethanol, Polysorbate 20, Purified Water, Pyridoxine Hydrochloride (Vitamin B6), Sodium Carbonate, Vernonia Amygdalina Bitter Leaf) Extract.	
QUESTIONS, COMMENTS: info@dyntone.com - 5054924611 - www.deepcoretherapy.com	
MADE IN USA. Distributed by: I-Fresh LLC, 5401 Lomas Blvd NE STE B Abq NM87110	




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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: T19T76XD44)
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.