

SOMBRA WARM THERAPY- menthol camphor gel
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.

Sombra Warm Therapy Natural Pain Relieving Gel

Active Ingredients

Menthol USP 3%, Camphor USP 3%

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

Warnings

For external use only. Do not use on wounds or damaged skin. **When using this product:** avoid bandaging tightly, avoid contact with eyes, **keep out of reach of children.**

Stop use and ask doctor if: condition worsens, symptoms persist for more than 7 days, clear up and occur again within a few days.

Directions

adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily, rub in thoroughly until gel is absorbed, **children under 2 years of age:** consult a doctor.

Inactive Ingredients

aloe barbadensis leaf juice, carbomer, decyl glucoside, purified water, citrus grandis (grapefruit) seed extract, camellia sinensis (green tea) leaf extract, citrus aurantium dulcis (orange) peel oil, filipendula ulmaria flower (queen of the prairie) extract, rosa

damascena flower water, sodium carbonate, glycerin, hamamelis virginiana (witch hazel) leaf extract, yucca schidigera stem extract, phenoxyethanol, caprylyl glycol, capsicum annuum fruit extract

Questions or Comments

1-800-225-3963

Drug Facts
Active Ingredients:
Camphor USP 3.0%
Menthol USP 3.0%
Uses:
Temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backaches ■ arthritis.
Warnings:
For external use only. Do not use on wounds or damaged skin or with a heat source. If pregnant or breastfeeding, ask a healthcare professional before use. When using this product: ■ avoid bandaging tightly ■ avoid contact with eyes ■ Keep out of reach of children. ▶

NDC 61577-3216-4
Purpose:
External analgesic
External analgesic

**SOMBRA.**
Warm Pain Relief
Arthritis & Back Pain
Net Wt. 4 oz. 113.7 g

Drug Facts (continued)
Stop Use and ask a doctor if: ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days.
Directions:
Adults and children 2 years of age and older: ■ apply to affected area not more than 3 to 4 times daily ■ rub in thoroughly until gel is absorbed. **Children under 2 years of age:** consult a doctor.
Inactive Ingredients: Aloe Barbadosensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Capsicum Annuum Fruit Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Grandis (Grapefruit) Seed Extract, Decyl Glucoside, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Yucca Schidigera Stem Extract.
Questions or Comments? 1-800-225-3963



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www.sombrausa.com • Made in the USA • Manufactured by Sombra® Wellness Products

SOMBRA WARM THERAPY

menthol camphor gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-3216
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
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
Inactive Ingredients			
Ingredient Name			Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)			
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)			
WATER (UNII: 059QF0KO0R)			
CAPSAICIN (UNII: S07O44R1ZM)			
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)			
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)			
SODIUM CARBONATE (UNII: 45P3261C7T)			
GLYCERIN (UNII: PDC6A3C0OX)			
WITCH HAZEL (UNII: 101I4J0U34)			
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)			
ORANGE PEEL (UNII: T19T76XD44)			

PHENOXYETHANOL (UNII: HIE492ZZ3T)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3216-1	3628.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2022	
2	NDC:61577-3216-2	907.2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2022	
3	NDC:61577-3216-3	226.8 g in 1 JAR; Type 0: Not a Combination Product	05/18/2022	
4	NDC:61577-3216-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	05/18/2022	
5	NDC:61577-3216-6	113.4 g in 1 TUBE; Type 0: Not a Combination Product	05/18/2022	
6	NDC:61577-3216-7	56.7 g in 1 JAR; Type 0: Not a Combination Product	05/18/2022	
7	NDC:61577-3216-9	5 g in 1 POUCH; Type 0: Not a Combination Product	05/18/2022	
8	NDC:61577-3216-5	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	05/18/2022	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment			
Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3216) , label(61577-3216)

Revised: 5/2022

SOMBRA COSMETICS INC.