

SOMBRA COOL THERAPY- menthol 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 Cool Therapy Natural Pain Relieving Gel

Active Ingredients

Menthol USP 6%

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 with: simple backaches, strains, bruises, and sprains

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, camellia sinensis (green tea) leaf extract, caprylyl glycol carbomer, citrus grandis (grapefruit) seed extract, citrus limon (lemon) peel oil, decyl glucoside, filipendula ulmaria flower (queen of the prairie) extract, glycerin, hamamelis virginiana (witch hazel) leaf extract, phenoxyethanol, purified water, rosa damascena flower water, sodium carbonate, yucca schidigera stem extract,

Question or comments

1-800-225-3963



SOMBRA.

Cool Pain Relief

Strains & Sore Muscles

Net Wt. 3 oz. 85.05 g

Drug Facts

NDC 61577-3221-5

Active Ingredient:
Menthol, USP 6.0%

Purpose:
External analgesic

Uses:

Temporarily relieves minor aches and pains of muscles and joints associated with: ■ strains ■ bruises ■ sprains.

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.

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, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, 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? 800-225-3963

Manufactured by Sombra® Wellness Products • 5951 Office Blvd. NE • Albuquerque, NM 87109
www.SombraUSA.com • Made in the USA

SOMBRA COOL THERAPY

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-3221
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.06 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)	
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)	
LEMON OIL (UNII: I9GRO824LL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3221-1	3628.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/17/2022	
2	NDC:61577-3221-2	907.2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/17/2022	
3	NDC:61577-3221-3	226.8 g in 1 JAR; Type 0: Not a Combination Product	05/17/2022	
4	NDC:61577-3221-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	05/17/2022	
5	NDC:61577-3221-6	113.4 g in 1 TUBE; Type 0: Not a Combination Product	05/17/2022	
6	NDC:61577-3221-7	56.7 g in 1 JAR; Type 0: Not a Combination Product	05/17/2022	
7	NDC:61577-3221-9	5 g in 1 POUCH; Type 0: Not a Combination Product	05/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/17/2022	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3221) , label(61577-3221)

Revised: 5/2022

SOMBRA COSMETICS INC.