

SOMBRA PLUS CBD 1000MG 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 Plux CBD 1000mg Cool Therapy

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 associated with: strains, bruises, and sprains

Warnings

For external use only. Do not use on wounds or damaged skin or with heat source. If you are pregnant or breastfeeding, consult a healthcare professional before use. **When using this product:** Avoid bandaging tightly, avoid contact with eyes, **keep out of reach children**

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, Cannabidiol (isolate), caprylyl glycol, carbomer, citrus grandis (grapefruit) seed extract, citrus limon (lemon) peel oil, decyl glucoside, glycerin, hamamelis virginiana (witch hazel) leaf extract, phenoxyethanol, purified water, rosa damascena flower water, sodium carbonate,

Filipendula ulmaria (queen of the prairie) flower extract, yucca schidigera root extract,

Questions or Comments

1-800-225-3963

Drug Facts NDC 61577-7100-2
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 you are pregnant or breastfeeding, consult a healthcare professional before use. When using this product: ■ avoid bandaging tightly ■ avoid contact with eyes. ■ Keep out of reach of children. ▶
 Net Wt. 2 oz. 56.7 g

THC-FREE

SOMBRA. PLUS CBD 1000mg Cool Pain Relief

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 Barbados Leaf Juice, Camellia Sinesis (Green Tea) Leaf Extract, Cannabidiol (Isolate), 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 Root Extract.
Questions or Comments? 1-800-225-3963

5801 Office Blvd, NE • Albuquerque, NM 87110 • 805-225-3963
 www.sombrapl.us.com • Made in USA • Manufactured by Sombra Wellness Products

SOMBRA PLUS CBD 1000MG COOL THERAPY

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-7100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.06 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: HIE492Z33T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CANNABIDIOL (UNII: 19GBJ60SN5)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-7100-2	56.7 g in 1 JAR; Type 0: Not a Combination Product	05/20/2022	
2	NDC:61577-7100-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	05/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/20/2022	

Labeler - Sombra Cosmetics Inc. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra COSMETICS INC		097464309	manufacture(61577-7100) , label(61577-7100)

Revised: 5/2022

Sombra Cosmetics Inc.