

## **SOMBRA PLUS CBD 1000MG 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.*

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## **Sombra Plus CBD 1000mg Warm Therapy**

### **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 Baradensis Leaf Juice, Camillia Sinensis (Green Tea) Leaf Extract, Cannabidiol (isolate), Caprylyl Glycol, Capsicum Annuum Fruit Extract, Carbomer, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Grandis (Grapefruit) Seed Extract, Decyl Glucoside,

Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rose Damascena Flower Water, Sodium Carbonate, Filipendula Ulmaris (Queen of the Prairie) Flower Extract, Yucca Schidigera Stem Extract.



## SOMBRA PLUS CBD 1000MG WARM THERAPY

menthol, camphor gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-7010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.03 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CAPSAICIN</b> (UNII: S07O44R1ZM)	
<b>GRAPEFRUIT SEED OIL</b> (UNII: 598D944HOL)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>FILIPENDULA ULMARIA FLOWER</b> (UNII: 06L18L32G6)	
<b>ROSA CENTIFOLIA FLOWER OIL</b> (UNII: H32V31VMWY)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WITCH HAZEL</b> (UNII: 101I4J0U34)	
<b>YUCCA SCHIDIGERA STEM</b> (UNII: N59C6T6D72)	
<b>ORANGE PEEL</b> (UNII: T19T76XD44)	
<b>PHENOXYETHANOL</b> (UNII: H1E492Z33T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-7010-2	56.7 g in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2022	
2	NDC:61577-7010-4	113.4 g in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/19/2022	

**Labeler** - Sombra Cosmetics INC (097464309)

### Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics INC		097464309	manufacture(61577-7010) , label(61577-7010)

Revised: 5/2022

Sombra Cosmetics INC