

**SOMBRA COOL THERAPY- menthol cream**  
**SOMBRA COSMETICS INC.**

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**ScripHessco Cool Therapy Pain Relief**

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

## Questions or Comments

1-800-225-3963



Made in USA • Manufactured by Sombra, Inc.



natural pain relieving gel

Net Wt. 3 oz. 85.05 g

5051 Office Blvd. NE • Albuquerque, NM 87109 • 800-225-3963 • www.sombraUSA.com

<b>Drug Facts</b>	NDC 61577-3221-5
<b>Active Ingredients</b> Menthol, USP 6.0%	<b>Purpose</b> External analgesic
<b>Uses</b> temporarily relieves minor aches and pains of muscles and joints associated with: ■ strains ■ bruises ■ sprains	
<b>Warnings</b> For external use only. Keep out of reach of children. Avoid contact with eyes. <b>Stop use and ask doctor if</b> ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ <b>When using this product:</b> avoid bandaging tightly	
<b>Directions</b> <b>Adults and children 2 years of age and older:</b> ■ apply to affected area not more than 3 to 4 times daily ■ rub in thoroughly until gel is absorbed <b>Children under 2 years of age:</b> consult a doctor.	
<b>Inactive Ingredients</b> 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, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Rosa Damascena Flower Water, Sodium Carbonate, Spiraea Ulmaria Flower (Queen of the Prairie) Extract, Water, Yucca Schidigera Root Extract.	
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## SOMBRA COOL THERAPY

menthol cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-3535
<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	0.06 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>WATER</b> (UNII: 059QF0K00R)	
<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 ROOT</b> (UNII: E2H9ET15AT)	
<b>LEMON OIL</b> (UNII: I9GRO824LL)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3535-7	3628.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/25/2026	
2	NDC:61577-3535-6	907.2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/25/2026	
3	NDC:61577-3535-3	226.8 g in 1 JAR; Type 0: Not a Combination Product	02/25/2026	
4	NDC:61577-3535-5	113.4 g in 1 TUBE; Type 0: Not a Combination Product	02/25/2026	
5	NDC:61577-3535-4	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/25/2026	
6	NDC:61577-3535-2	113.4 g in 1 JAR; Type 0: Not a Combination Product	02/25/2026	
7	NDC:61577-3535-1	56.7 g in 1 JAR; Type 0: Not a Combination Product	02/25/2026	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/29/2016	

**Labeler** - SOMBRA COSMETICS INC. (097464309)

## Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3535) , label(61577-3535)

Revised: 2/2026

SOMBRA COSMETICS INC.