

**NVCARE- 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.*

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**NV Care 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: 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



<b>Drug Facts</b>	NDC 61577-5320-1
<b>Active Ingredient:</b> Menthol, USP 8.0%	<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. Do not use on wounds or damaged skin or with a heat source. If 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.	



**NATURAL PAIN RELIEVING GEL**

**Care™ COOL THERAPY**

Net Wt. 8oz. 226.8 g      571-502-9989      [nguyuradio.com](http://nguyuradio.com)

0763 Wilson Blvd. #6 Falls Church, VA 22044      MADE IN U.S.A.

<b>Drug Facts (continued)</b>
<b>Stop use and ask doctor if:</b> ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days.
<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 Siroaldensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, Dicyl Glucoside, Filipendula Ulmaria (Queen of the Prairie) Extract, Glycyrrhiza, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbamate, Yucca Schidigera Root Extract.
<b>Questions or Comments?</b> 571-502-9989 • <a href="http://nguyuradio.com">nguyuradio.com</a>

## NVCARE

menthol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-5320
<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: 059QF0KO0R)	
<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: H1E492ZZ3T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-5320-1	226.8 g in 1 JAR; Type 0: Not a Combination Product	03/08/2023	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/08/2023	

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

### Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-5320) , label(61577-5320)

Revised: 3/2023

SOMBRA COSMETICS INC.