

## **HEALQU WARM THERAPY GEL- 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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### **HealQu Warm Therapy Gel**

#### **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 barbadensis leaf juice, carbomer, decyl glucoside, water, citrus grandis (grapefruit) seed extract, camellia sinensis (green tea) leaf extract, citrus aurantium dulcis (orange) 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, capsicum annuum fruit extract

## Questions or Comments

1-800-225-3963

**Drug Facts** NDC 61577-4080-1

**Active Ingredients:** Camphor, USP 1.0%  
Menthol, USP 3.0%

**Purpose:** External analgesic  
External anesthetic

**Uses:** Temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backaches ■ arthritis.

**Warnings:**  
For external use only. Do not use on wounds or damaged skin. If pregnant or breastfeeding, consult a healthcare professional before use. Do not use with external heat. 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 ■ chills up and occurs again within a few days.

**HEALQU<sup>®</sup>**  
warm therapy gel

natural pain relief  
• relieves arthritis & joint pain  
• soothes sore muscles

Net Wt. 8 oz. 226.8 g

HEALQU pain relief gel contains only the finest natural ingredients to help deliver pain relief fast! Our gel is manufactured in the USA, contains no animal products, is non-staining and alcohol free.

Experience the finest in natural warm gel therapy pain relief

**Drug Facts (continued)**

**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 Barbadosis (Aloe Vera) Leaf Juice, Camellia Sinensis Green Tea Leaf Extract, Caprylyl Glycol, Capsicum Annuum Fruit Extract, Carbomer, Citrus Aurantium Peel Oil, Citrus Glucoside (Grapefruit Seed Extract), Oxyol Glucoside, Filipendula Ulmaria (Queen of the Pasture) Extract, Glycine, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Purified Water, Rosa Damascena Flower Water, Sedaria, Cascarilla, Yucca Schidigera Stem Extract.

Questions or Comments 77-844-4HEALQU Dist. by: HEALQU

## HEALQU WARM THERAPY GEL

menthol camphor gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-4080
<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>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<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 ROOT</b> (UNII: E2H9ET15AT)	
<b>ORANGE PEEL</b> (UNII: T19T76XD44)	
<b>PHENOXYETHANOL</b> (UNII: H1E492ZZ3T)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-4080-1	226.8 g in 1 JAR; Type 0: Not a Combination Product	03/09/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/09/2023	

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

### Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-4080) , label(61577-4080)

Revised: 3/2023

SOMBRA COSMETICS INC.