

**SOMBRA 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 Warm Therapy Natural Pain Relieving Gel Canada**

**Active Ingredients**

Menthol USP 3%, Camphor USP 3%

**Purpose**

Purpose  
External Analgesic

**Keep out of reach of children**

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**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



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**SOMBRA**  
Warm Pain Relief  
Soulagement  
de la Douleur à Chaud

NPN 80064419      Net Wt. 3 oz. 85.05 g

**Each dose contains:** Camphor 3%, Menthol 3%. **Chaque dose contient:** Camphre 3%, Menthol 3%.

Temporarily relieves aches and pains of muscles and joints associated with lumbago, and arthritis. Soulage temporairement les douleurs musculaires et articulaires associées au lumbago et à l'arthrite. **For external use only.** Avoid contact with the eyes and mucous membranes. Do not apply to wounds or damaged skin. Do not tightly bandage. Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn. Consult a health care practitioner for use beyond 7 days - If symptoms persist and/or worsen after 7 days or re-occur within a few days, discontinue use and consult a health care practitioner. **Keep out of the reach of children.** If overdose or accidental ingestion occurs, call a Poison Control Center immediately. If you are pregnant or breastfeeding, consult a health care practitioner prior to use. Store in airtight, light resistant container at room temperature. Hypersensitivity, itches and/or burning discomfort have been known to occur; in which case, discontinue use. If you experience pain, swelling or itching, stop use and get medical help right away. **Pour usage externe seulement.** Éviter tout contact avec les yeux ou les muqueuses. Ne pas appliquer sur une blessure ni sur une peau irritée. Ne pas appliquer en permanence sur une plaie. Ne pas appliquer du stéroïde externe comme un onguent ou du produit électrique, peut avoir comme résultat une irritation excessive ou des brûlures de la peau. Consulter un praticien de soins de santé pour un usage de plus de 7 jours. Si les symptômes s'aggravent après 7 jours ou réapparaissent ensuite quelques jours plus tard, cesser l'emploi et consulter un praticien de soins de santé. En cas de surdosage ou d'ingestion accidentelle, communiquer immédiatement avec un centre antipoison. Consulter un praticien de soins de santé avant d'en faire l'usage si vous êtes enceinte ou allaitement maternel. Ranger dans un contenant opaque étanche à l'air, à la température ambiante. En cas d'hypersensibilité, d'irritation et/ou de sensation de brûlure, cesser l'usage. En cas de douleur, urticaire, cloque, sensation d'irritation et absence de l'aide médicale immédiatement.

**Directions:** Adults, adolescents, and children 2 years+ apply thinly and evenly to affected areas up to 3-4 times per day. Rub and/or massage into skin until solution vanishes. Application for children under 12 should be supervised by an adult. **Note d'emploi:** Adultes, adolescents et enfants âgés de 2 ans et plus: Appliquer une couche mince et uniforme sur la zone affectée, jusqu'à 3 ou 4 fois par jour. Frotter et/ou masser la peau jusqu'à ce que le produit disparaisse. L'application chez les enfants de moins de 12 ans doit être supervisée par un adulte. **No medicinal ingredients:** d'oe herbicides: leaf joint, camellia sinensis (green tea) leaf extract, caprylyl glycol, capsicum annuum fruit extract, carbonic citrus aurantium dulcis (orange) peel oil, citrus grandis (grapefruit) seed extract, decyl glucoside, Euphorbia ulmaria (queen of the meadow) flower extract, glycerin, hamamelis virginiana (witch hazel) leaf extract, phenoxyethanol, purified water, rose damascena flower water, sodium carbonate, yucca schidigera stem extract. **Ingredients non médicamenteux:** jus de feuille d'Albe (aristotele), extrait de feuille de Camellia sinensis (thé vert), caprylyl glycol, extrait de fruit de Capsicum annuum, carthage, huile d'orange de Citrus aurantium dulcis (orange), extrait de pépites de Citrus grandis (pamplemousse), extrait de pépites de Citrus sinensis, décyl glucoside, Euphorbia ulmaria (reine des prés) extrait de fleur, glycérol, extrait de feuille d'Hamamelis virginiana (hamamelis), phénoxyéthanol, eau purifiée, eau de fleur de Rose damascena, carbonates de sodium (aristotele), extrait de Styracis albanicus, extrait de tige de Yucca schidigera.

Questions or Comments? 800-225-3963 • Importer: Medline Enterprises Inc., 1044 Botes Court, Mississauga, ON L4R3P4 • www.medline.ca  
Made in the USA • Manufactured by Sombra® Wellness Products

## SOMBRA WARM THERAPY

menthol camphor gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61577-4020
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		0.025 g

<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>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)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-4020-1	3628.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/10/2023	
2	NDC:61577-4020-2	907.2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/10/2023	
3	NDC:61577-4020-3	226.8 g in 1 JAR; Type 0: Not a Combination Product	03/10/2023	
4	NDC:61577-4020-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	03/10/2023	
5	NDC:61577-4020-5	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/10/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/10/2023	

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

### Establishment

Name	Address	ID/FEI	Business Operations

SOMBRA COSMETICS INC.

097464309

manufacture(61577-4020) , label(61577-4020)

Revised: 3/2023

SOMBRA COSMETICS INC.