

**SORE NO MORE WARM THERAPY PLUS CBD 500MG NATURAL PAIN RELIEVING 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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**Sore No More Warm Therapy Plus CBD 500mg Natural Pain Relieving Gel**

**ACTIVE INGREDIENTS**

MENTHOL USP 3%, CAMPHOR USP 3%

**PURPOSE**

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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: SIMPLE BACKACHES

**WARNINGS**

**FOR EXTERNAL USE ONLY. DO NOT USE ON WOUNDS OR DAMAGED SKIN. WHEN USING THIS PRODUCTS: AVOID BANDAGING TIGHTLY, AVOID CONTACT WITH EYES, KEEP OUT OF REACH OF CHILDREN.**

**STOP USE AND ASK DOCTOR IF:** CONDITION WORSENS, SYMPTONS 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, cannabidiol, capsicum annuum fruit extract,

**Question or comments**

1-800-225-3963

<p><b>Drug Facts</b> NDC 61577-7055-4</p> <p><b>Active Ingredients:</b> Camphor, USP 3.0% Menthol, USP 3.0%</p> <p><b>Uses:</b> Temporarily relieves minor aches and pains of muscles and joints associated with: ■ simple backaches ■ arthritis.</p> <p><b>Warnings:</b> For external use only. Do not use on wounds or damaged skin or with a heat source. If you are 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.</p> <p>5951 Office Blvd. NE • Albuquerque, NM 87109 • 800-225-3963 • www.SoreNoMorePlus.com</p>	<p><b>Purpose:</b> External analgesic External analgesic</p> <p><b>SORE NO MORE</b></p> <p>natural pain relieving gel</p> <p>NET WT. 4 OZ. 113.4 G</p>	<p><b>Plus 500mg CBD</b></p> <p><b>WARM THERAPY</b></p>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if:</b> ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days.</p> <p><b>Directions:</b> 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.</p> <p><b>Inactive Ingredients:</b> Aloe Barbadosensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Carnabidiol (Isolate), 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, Phenoxylethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, Yucca Schidigera Root Extract.</p> <p><b>Questions or Comments?</b> 1-800-225-3963</p>	<p>SPOT UV KNOCKOUT</p>  <p>7 63669 03200 2</p>
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menthol camphor gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:6 1577-7055
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
WATER (UNII: 059QF0K00R)	
CAPSAICIN (UNII: S07O44R1ZM)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
GREEN TEA LEAF (UNII: W2ZU1R8B0)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
GLYCERIN (UNII: PDC6A3C0OX)	
WITCH HAZEL (UNII: 101I4J0U34)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	
ORANGE PEEL (UNII: T19T76XD44)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-7055-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	11/03/2020	
2	NDC:61577-7055-2	56.7 g in 1 JAR; Type 0: Not a Combination Product	11/03/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/03/2020	

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

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-7055) , label(61577-7055)

Revised: 11/2020

SOMBRA COSMETICS INC.