# SORE NO MORE COOL THERAPY- 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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#### Sore No More Cool Therapy Natural Pain Relieving Gel Canada

#### **Active Ingredients**

Menthol USP 6%

#### **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.

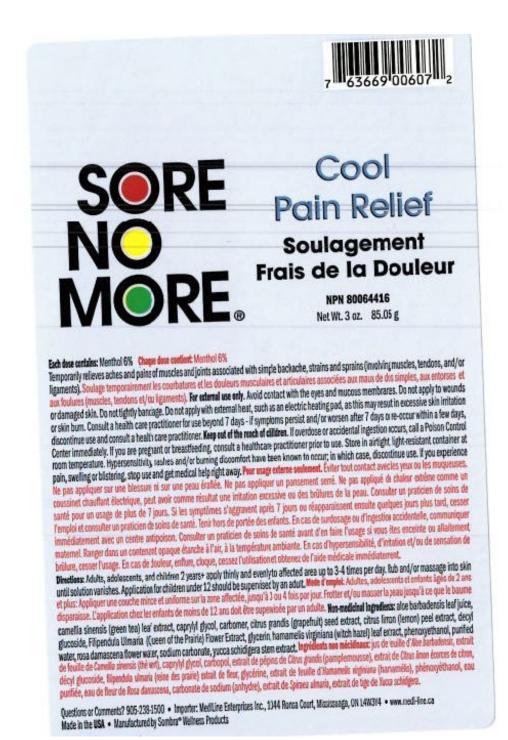
## **Inactive Ingredients**

aloe barbadensis leaf juice, carbomer, decyl glucoside, water, citrus grandis (grapefruit) seed extract, camellia sinensis (green tea) leaf extract, citrus 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



#### SORE NO MORE COOL THERAPY

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-4050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.06 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: 059QF0KO0R)			
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
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: TI9T76XD44)			
LEMON OIL (UNII: 19GRO824LL)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			

ı	Packaging				
7	tem Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:61577- 4050-2	907.2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/03/2023		
2	NDC:61577- 4050-3	226.8 g in 1 JAR; Type 0: Not a Combination Product	03/03/2023		
3	NDC:61577- 4050-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	03/03/2023		
4	NDC:61577- 4050-5	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/03/2023		

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

## Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment				
Name	Address	ID/FEI	Business Operations	
SOMBRA COSMETICS INC.		097464309	manufacture(61577-4050), label(61577-4050)	

Revised: 3/2023 SOMBRA COSMETICS INC.