

SORE NO MORE COOL THERAPY- menthol gel
SOMBRA COSMETICS INC.

Sore No More Cool Therapy Natural Pain Relieving Gel

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:
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**

Natural Pain
Relieving Gel

**COOL
THERAPY**

Net Wt. 3 oz 85g

Drug Facts	NDC 61577-3235-5
Active Ingredients Menthol, USP 6.09%	Purpose External analgesic
Uses temporarily relieves minor aches and pains of muscles and joints associated with: ■ strains ■ bruises ■ sprains	
Warnings For external use only. Keep out of reach of children. Avoid contact with eyes. Stop use and ask doctor if ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ When using this product: avoid bandaging tightly	
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, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, Decyl Glucoside, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxyethanol, Rosa Damascena Flower Water, Sodium Carbonate, Spiraea Ulmaria Flower (Queen of the Prairie) Extract, Water, Yucca Schidigera Root Extract.	
Questions or Comments? 1-800-225-3963 • Made in USA Manufactured by Sombra, Inc. • www.sorenomoreUSA.com	

SORE NO MORE COOL THERAPY

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-3235
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: I9GRO824LL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3235-2	907.2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/14/2016	
2	NDC:61577-3235-8	28.3 g in 1 JAR; Type 0: Not a Combination Product	07/02/2017	
3	NDC:61577-3235-1	226.8 g in 1 JAR; Type 0: Not a Combination Product	06/14/2016	
4	NDC:61577-3235-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	06/14/2016	
5	NDC:61577-3235-5	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/14/2016	
6	NDC:61577-3235-6	113.4 g in 1 TUBE; Type 0: Not a Combination Product	06/14/2016	
7	NDC:61577-3235-7	56.7 g in 1 JAR; Type 0: Not a Combination Product	06/14/2016	
8	NDC:61577-3235-9	5 g in 1 POUCH; Type 0: Not a Combination Product	06/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/14/2016	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3235) , label(61577-3235)

Revised: 5/2025

SOMBRA COSMETICS INC.