

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.

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

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

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SORE NO MORE®

Cool Pain Relief

Soulagement Frais de la Douleur

NPN 80064416
Net Wt. 3 oz. 85.05 g

Each dose contains: Menthol 6% *Chaque dose contient: Menthol 6%*
Temporarily relieves aches and pains of muscles and joints associated with simple backache, strains and sprains (involving muscles, tendons, and/or ligaments). *Soulage temporairement les courbatures et les douleurs musculaires et articulaires associées aux maux de dos simples, aux entorses et aux foulures (muscles, tendons et/ou ligaments).* **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 healthcare practitioner prior to use. Store in airtight, light-resistant container at room temperature. Hypersensitivity, rashes and/or burning discomfort have been known to occur; in which case, discontinue use. If you experience pain, swelling or blistering, 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 éraflée. Ne pas appliquer un pansement serré. Ne pas appliquer de chaleur externe comme un coussinet chauffant 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. Tenir hors de portée des enfants. 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, enflure, cloque, cessez l'utilisation et obtenez de l'aide médicale immédiatement.

Directions: Adults, adolescents, and children 2 years+ apply thinly and evenly to affected area 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. **Mette 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 baume disparaisse. L'application chez les enfants de moins de 12 ans doit être supervisée par un adulte. **Non-médical ingredients:** aloe barbadensis leaf juice, camellia sinensis (green tea) leaf extract, caprylyl glycol, carbomer, citrus grandis (grapefruit) seed extract, citrus limon (lemon) peel extract, decyl glucoside, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, glycerin, hamamelis virginiana (witch hazel) leaf extract, phenoxyethanol, purified water, rosa damascena flower water, sodium carbonate, yucca schidigera stem extract. **Ingredients non médicaux:** jus de feuille d'Aloe barbadensis, extrait de feuille de Camellia sinensis (thé vert), caprylyl glycol, carbopol, extrait de pépins de Citrus grandis (pamplemousse), extrait de Citrus limon écorces de citron, décyyl glucoside, Filipendula ulmaria (rose des prairies) extrait de fleur, glycérine, extrait de feuille d'Hamamelis virginiana (hamamélis), phénoxyéthanol, eau purifiée, eau de fleur de Rosa damascena, carbonate de sodium (anhydre), extrait de Spiraea ulmaria, extrait de tige de Yucca schidigera.

Questions or Comments? 905-238-1500 • Importer: MediLine Enterprises Inc., 1344 Ronsa Court, Mississauga, ON L4W3V4 • www.med-line.ca
Made in the USA • Manufactured by Sombra® Wellness Products

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: I9GRO824LL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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.