

SORE NO MORE- 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.

SORE NO MORE

Active Ingredients

Menthol USP 3%

Camphor USP 3%

Purpose

External Analgesic

Keep out of reach of children

Keep out of reach of children

Uses

Temporarily relieves minor aches, pains, inflammation and sore muscles associated with stiffness, arthritis, and injuries

Warnings

For external use only. Avoid contact with eyes, mucous membranes, damaged skin. Do not use with heating pads, avoid bandaging tightly.

Stop use and ask doctor if: symptoms persist

Directions

adults and children 2 years of age and older: apply to affected area liberally up to 4 times daily. Avoid contact with eyes. Wash hands after use.

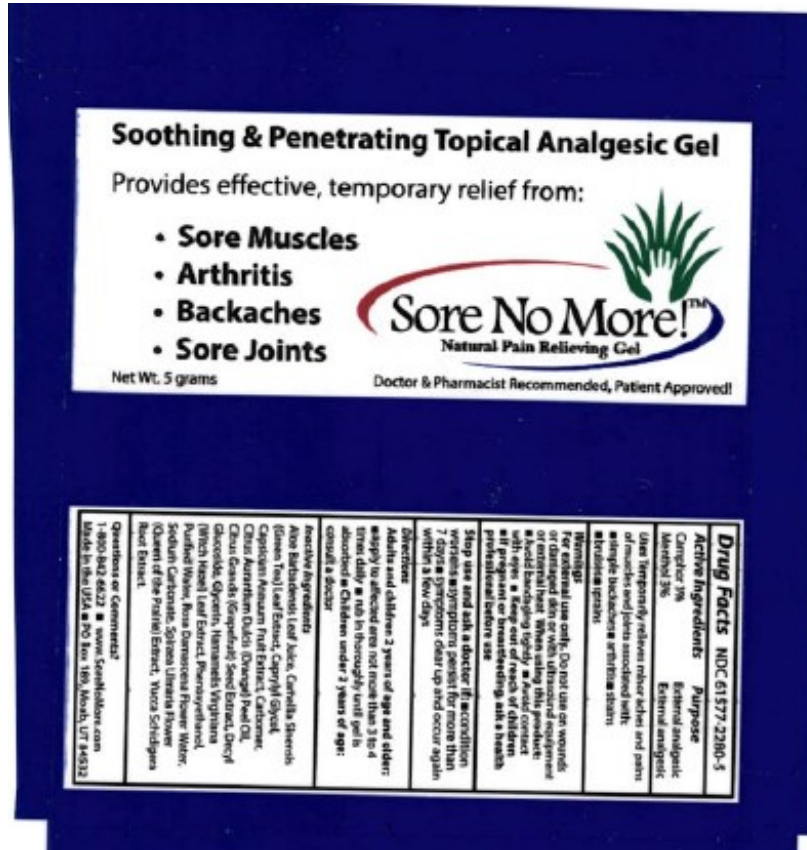
Inactive Ingredients

Aloe Barbadensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Caprylyl Glycol, 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, Phenoxyethanol,

Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Spiraea Ulmaria Flower (Queen of the Prairie) Extract, Yucca Schidigera Root Extract

Questions or Comments

1-800-842-6622



SORE NO MORE

menthol camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-2280
Route of Administration	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)	
CAPSICUM (UNII: 00UK7646FG)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
WATER (UNII: 059QF0KO0R)	
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ORANGE PEEL (UNII: T19T76XD44)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
GLYCERIN (UNII: PDC6A3C0OX)	
WITCH HAZEL (UNII: 101I4J0U34)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-2280-5	5 g in 1 POUCH; Type 0: Not a Combination Product	03/08/2023	
2	NDC:61577-2280-2	58.7 g in 1 JAR; Type 0: Not a Combination Product	03/08/2023	
3	NDC:61577-2280-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	03/08/2023	
4	NDC:61577-2280-8	226.8 g in 1 JAR; Type 0: Not a Combination Product	03/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/08/2023	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-2280) , label(61577-2280)

Revised: 3/2023

SOMBRA COSMETICS INC.