

MUSCLE EASE- 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.

Muscle Ease

Active Ingredients

Menthol USP 3%

Camphor USP 3%

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: simple backaches, arthritis, strains, bruises, and sprains

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, 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, 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.

Questions or Comments

1-800-225-3963

**muscle ease gel
with botanical
pain relievers**
provides temporary relief
from minor aches and pains



clean skin for a radiant life®
Net wt 2 oz / 56 g

NDC 61577-2301-2

Active ingredients	Purpose
Camphor, USP 3.0%.....	External Analgesic
Menthol, USP 3.0%.....	External Analgesic

Uses • temporarily relieves minor aches and pains of muscles and joints associated with: • simple backaches
• arthritis • strains • bruises • sprains

Warnings
For external use only. Do not use on wounds or damaged skin. If pregnant or breastfeeding, ask a healthcare professional before use. Do not use with external heat. 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
• symptoms 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 Barbadosensis 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 Extract, Yucca Schidigera Root Extract.

Questions or Comments? 877-6-LATHER

Free of parabens, sulfates, mineral oil and synthetic fragrance and colors. No animal testing.

Distributed by LATHER, Inc.
Pasadena, CA 91105
877-6-LATHER
www.lather.com
Made in USA

packaging made with




8 36583 00230 4 84

MUSCLE EASE

menthol camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61577-2301
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)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ORANGE PEEL (UNII: T19T76XD44)	
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
GLYCERIN (UNII: PDC6A3C0OX)	
WITCH HAZEL (UNII: 101I4J0U34)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CARBONATE (UNII: 45P3261C7T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-2301-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	02/14/2023	
2	NDC:61577-2301-2	56.7 g in 1 TUBE; Type 0: Not a Combination Product	02/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/14/2023	

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

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-2301) , label(61577-2301)

Revised: 2/2023

SOMBRA COSMETICS INC.