# 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.

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### 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.

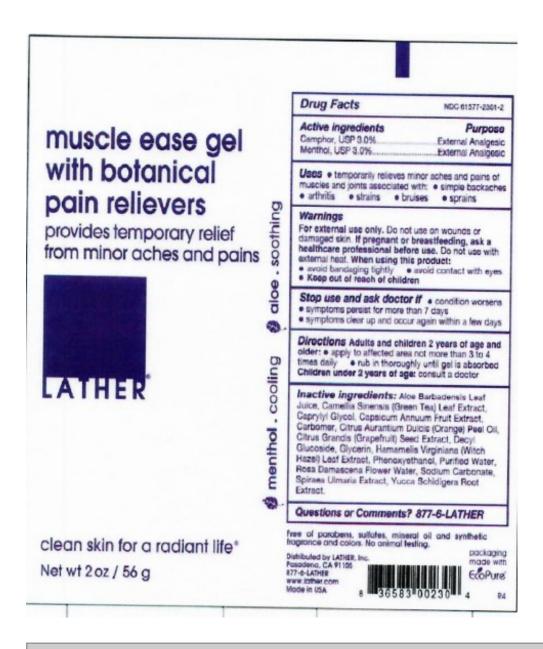
# **Inactive Ingredients**

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 Praire) 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 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: TI9T76XD44)	
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 Marketing E		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.