DEEP REMEDY- 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.

Deep Remedy Natural Pain Relieving Gel

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 vera extract, capsaicin, carbomer, decyl polyglucose, deinoized water, grapefruit seed extract, green tea extract, orange peel extract, queen of the prairie extract, rose

water, sodium hydroxymethylglycinate, vegetable glycerin, witch hazel, yucca extract

Questions or Comments

1-800-225-3963

DEEP REMEDY

menthol camphor gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61577-3610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A, MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.03 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	.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: TI9T76XD44)	
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:61577-3610-5	5 g in 1 POUCH; Type 0: Not a Combination Product	12/23/2021	
2	NDC:61577-3610-2	58.7 g in 1 JAR; Type 0: Not a Combination Product	12/23/2021	
3	NDC:61577-3610-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	12/23/2021	
4	NDC:61577-3610-8	226.8 g in 1 JAR; Type 0: Not a Combination Product	12/23/2021	
5	NDC:61577-3610-1	14.2 g in 1 JAR; Type 0: Not a Combination Product	12/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2021	

Labeler - SOMBRA COSMETICS INC. (097464309)

Registrant - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC.		097464309	manufacture(61577-3610) , label(61577-3610)

Revised: 12/2021 SOMBRA COSMETICS INC.