

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, deionized 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

Drug Facts		NDC 61557-361-04			Natural Pain Relieving Gel Analgesico Natural Net Wt. 4 oz. 113.6 g	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 areas 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, deionized 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? 1-855-533-5975 Made in U.S.A. Distributed by Deep Remedy, Inc. www.deepremedy.com	
Active Ingredients	Purpose						
Camphor, USP 3.0% Menthol, USP 3.0%	External analgesic 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 wound or damaged skin. When using this product: ■ avoid bandaging tightly ■ avoid contact with eyes ■ Keep out of reach of children							

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DEEP REMEDY

menthol camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1577-36 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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: 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:6 1577-36 10-5	5 g in 1 POUCH		

2	NDC:61577-3610-2	58.7 g in 1 JAR		
3	NDC:61577-3610-4	113.4 g in 1 JAR		
4	NDC:61577-3610-8	226.8 g in 1 JAR		
5	NDC:61577-3610-1	14.2 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/01/2013	

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: 1/2013

SOMBRA COSMETICS INC.