# DEEP REMEDY - menthol and camphor (synthetic) 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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## **Deep Remedy Natural Pain Relieving Gel**

### **Active Ingredients**

Menthol USP 3%

Camphor USP 3%

### **Purpose**

Purpose

External Analgesic

## Keep out of reach of children

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#### 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

## deep30001.jpg

## **DEEP REMEDY**

menthol camphor gel

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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (MENTHOL)	MENTHOL	.03 g in 1 g	
CAMPHOR (SYNTHETIC) (CAMPHOR (SYNTHETIC))	CAMPHOR (SYNTHETIC)	.03 g in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF		
CAPSICUM		
CARBOMER HOMOPOLYMER TYPE C		
DECYL GLUCOSIDE		
WATER		
GRAPEFRUIT SEED OIL		
GREEN TEA LEAF		
O RANGE PEEL		
FILIPENDULA ULMARIA FLOWER		
ROSA CENTIFOLIA FLOWER OIL		
SO DIUM HYDRO XYMETHYLGLYCINATE		
GLYCERIN		
WITCH HAZEL		
YUCCA SCHIDIGERA ROOT		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3610-5	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	0 1/0 1/20 13	

## 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.