

## **DREAM CREAM- camphor, menthol cream**

### **Little Moon Essentials**

*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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## **Drug Facts**

### **Active Ingredients**

Camphor 0.45%

Menthol 5%

### **Purpose**

Topical Analgesic

### **Uses**

Uses temporarily relieves minor pain associated with

- simple backache
- muscle strains
- sprains
- bruises

### **Warning**

#### **For external use only**

#### **When using this product**

- Use only as directed
- Read and follow all directions and warnings on this label
- Rare cases of serious burns have been reported with products of this type
- Do not bandage tightly or apply local heat (such as heating pads) or medicated patches to the area of use
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds or damages, broken or irritated skin
- A transient burning sensation may occur upon application but generally disappears in several days

#### **Stop use and ask a doctor**

- Condition worsens
- Redness is present
- Irritation develops
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

#### **If pregnant or breast feeding**

Ask a health professional before use.

## **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away

## **Directions**

### **Adults and children over 12 years:**

- Apply a thin layer to affected area
- Massage into painful area until thoroughly absorbed into skin repeat as necessary, but no more than 3 to 4 times daily, allowing minimum of 2-3 hours between applications
- **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**

**Children 12 years or younger:** ask a doctor

## **Other information**

Store at 68-77°F (20-25°C)

Protect from excessive moisture

## **Inactive Ingredients**

Water (aqua)

organic safflower oil (*carthamus tinctorius*)

beeswax (*cera alba*)

cetearyl olivate

arnica oil (*arnica montana*)

castor oil (*ricinus communis*)

cetearyl alcohol

wintergreen oil (*gaultheria procumbens*)

xanthan gum

cinnamon oil (*cinnamomum zeylanicum*)

lavender oil (*lavandula angustifolia*)

cyprus oil (*cupressus sempervirens*)

eucalyptus blue mallee oil

marjoram (*thymus mastichina*)

rosemary oil (*rosmarinus officinalis*)

juniper oil (*juniperus communis*)

magnesium aluminum silicate

immortelle oil (*helichrysum angustifolium*)

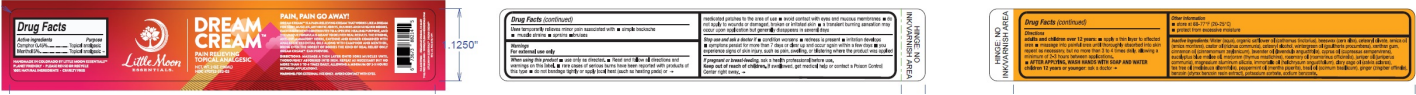
clary sage oil (*salvia sclarea*)

tea tree oil (*melaleuca alternifolia*)

peppermint oil (*mentha piperita*)

basil oil (ocimum basilicum)  
ginger (zingiber officinale)  
benzoin (styrax benzoin resin extract)  
potassium sorbate  
sodium benzoate

Principle Display Panel 56.7 g container



DREAM CREAM			
camphor, menthol cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70722-232
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	5 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)		CAMPHOR (NATURAL)	0.45 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
SAFFLOWER OIL (UNII: 65UEH262IS)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CETEARYL OLIVATE (UNII: 58B69Q84JO)			
ARNICA MONTANA (UNII: O80TY208ZW)			
CASTOR OIL (UNII: D5340Y2I9G)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
XANTHAN GUM (UNII: TTV12P4NEE)			
CINNAMON OIL (UNII: E5GY4I6YCZ)			
SWEET MARJORAM (UNII: G9Z40ZYU6P)			
GINGER (UNII: C5529G5JPQ)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
LAVENDER OIL (UNII: ZBP1YXW0H8)			
CUPRESSUS SEMPERVIRENS LEAF OIL (UNII: M7QUY89S4O)			
EUCALYPTUS POLYBRACTEA LEAF OIL (UNII: J1XGA6WROO)			
ROSEMARY OIL (UNII: 8LGU7VM393)			

JUNIPER BERRY OIL (UNII: SZH16H44UY)				
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)				
PSEUDOGNAPHALIUM LUTEOALBUM WHOLE (UNII: HR514FFZ7I)				
CLARY SAGE OIL (UNII: 87L0D4U3M0)				
TEA TREE OIL (UNII: VIF565UC2G)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
BASIL OIL (UNII: Z129UMU8LE)				
BENZOIN RESIN (UNII: GK21SBA74R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-232-02	56.7 g in 1 CONTAINER; Type 0: Not a Combination Product	10/04/2016	
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part348	10/04/2016	

**Labeler** - Little Moon Essentials (840835115)

**Registrant** - Little Moon Essentials LLC (840835115)

Establishment			
Name	Address	ID/FEI	Business Operations
Little Moon Essentials LLC		840835115	manufacture(70722-232)