

## **ACHING HEAD RUB- camphor, menthol ointment**

### **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 3.09%

Menthol 2.55%

#### **Purpose**

Topical Analgesic

#### **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 a 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 damaged skin, broken or irritated skin
- A transient burning sensation may occur upon application but generally disappears in several days.

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

- 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 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 daily
- Repeat as necessary, but no more than 3 to 4 times daily, allowing a 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**

Organic sesame oil (Sesamum Indicum)

Organic Olive oil (Olea Europaea)

Organic Ginger Powder( Zingiber officinales)

Organic Castor oil (Ricinus Communis)

Beeswax (Cera Alba)

Wintergreen oil (Gaultheria Procumbens)

Marjoram (Thymus Mastichina)

Cinnamon oil (Cinnamomum Zeynalicum)

Lavender oil (Lavandula Angustifolia)

Eucalytus globulus

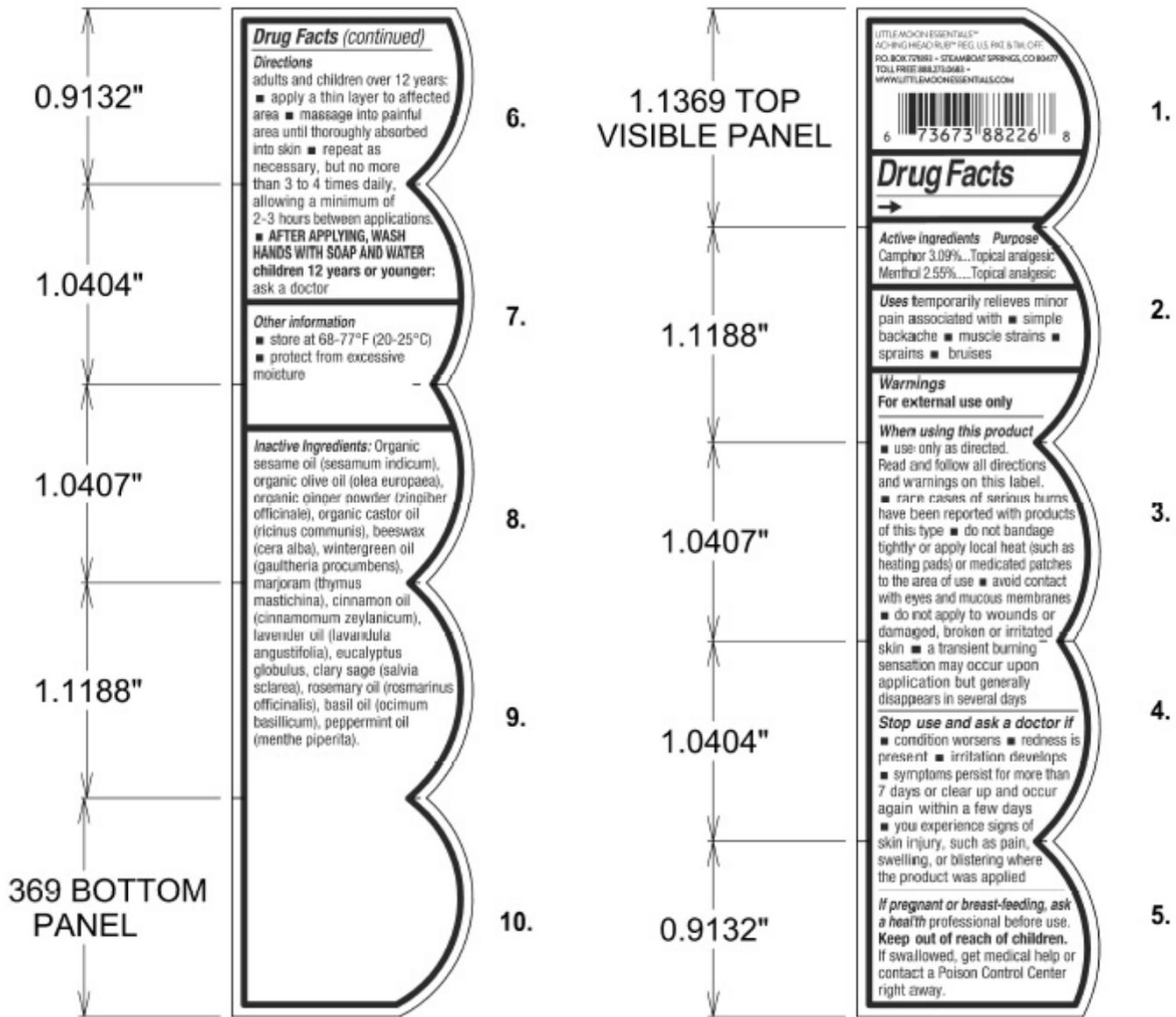
Clary sage (Salvia Sclarea)

Rosemary oil(Rosmarinus Officinalis)

Basil oil (Ocimum basilicum)

Peppermint oil (Mentha Piperita)

**Principle Display Panel- 14g Container**



## ACHING HEAD RUB

camphor, menthol ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70722-203
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2.55 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	3.09 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GINGER OIL (UNII: SAS9Z1SVUK)	
CASTOR OIL (UNII: D5340Y2I9G)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SWEET MARJORAM OIL (UNII: ICH7BE016E)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
CLARY SAGE (UNII: U3HSK5JC0Q)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
BASIL OIL (UNII: Z129UMU8LE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SESAME OIL (UNII: QX10HYY4QV)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-203-05	14 g in 1 CONTAINER; Type 0: Not a Combination Product	09/28/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	09/26/2016	

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

Name	Address	ID/FEI	Business Operations
Little Moon Essentials LLC		840835115	manufacture(70722-203)