

**VITAL VAPOR- 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 0.6%

Menthol 5.2%

**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 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 damaged, 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 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 officinale*)

organic castor oil (*ricinus communis*)

beeswax (*cera alba*)

eucalyptus *staigeriana*

tea tree oil (*melaleuca alternifolia*)

wintergreen oil (*gaultheria procumbens*)

eucalyptus *globulus* oil

lemongrass oil (*cymbopogon citratus*)

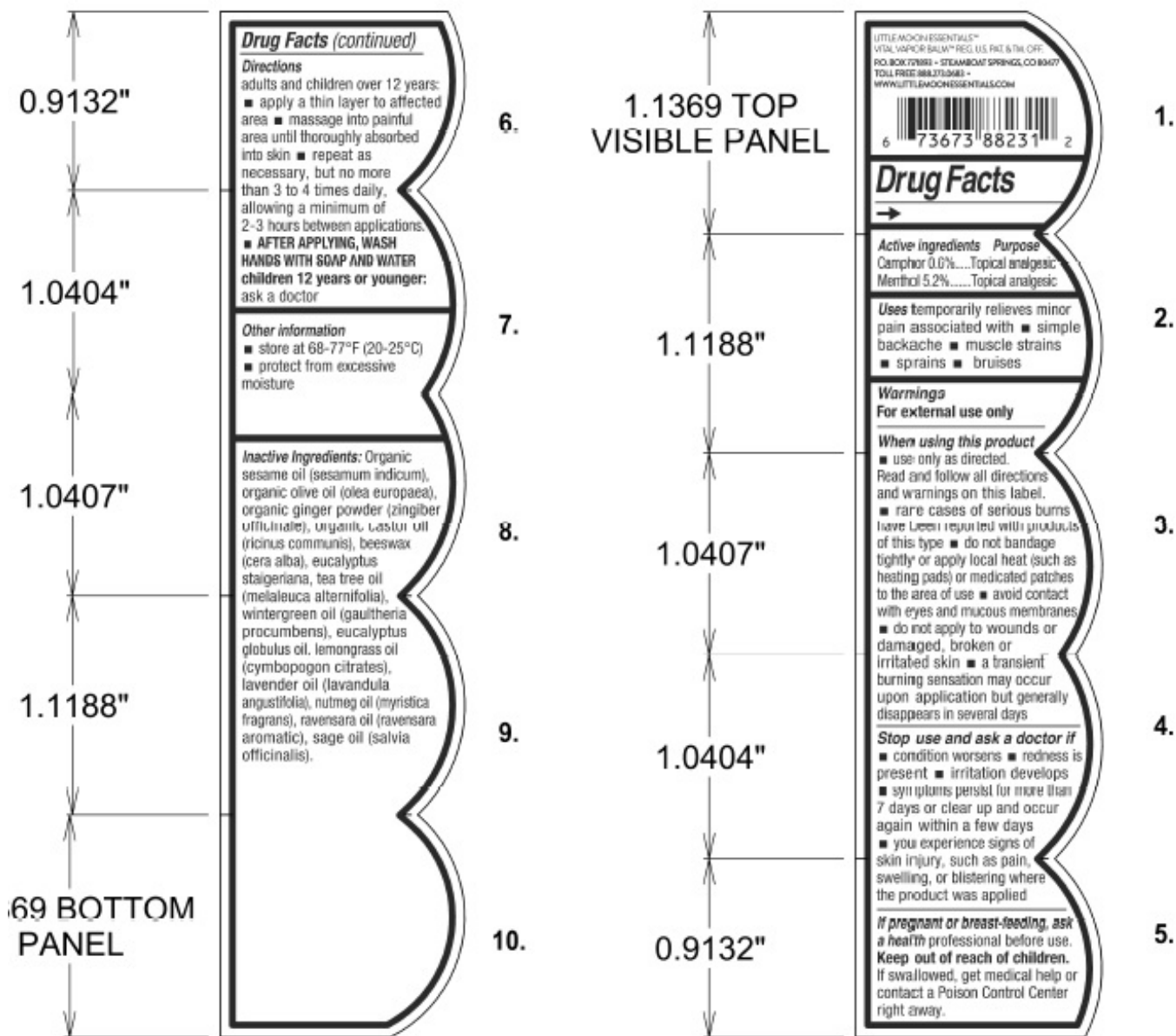
lavender oil (*lavandula angustifolia*)

nutmeg oil (*myristica fragrans*)

ravensara oil (*ravensara aromatic*)

sage oil (*salvia officinalis*)

## **Principle Display Panel 14g container**



**VITAL VAPOR**  
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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:7022-229
<b>Route of Administration</b>	TOPICAL		

<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	5.2 g in 100 g	
	<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.6 g in 100 g	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	<b>WEST INDIAN LEMONGRASS OIL</b> (UNII: 5BIA40E9ED)			
	<b>NUTMEG OIL</b> (UNII: Z1CLM48948)			
	<b>SAGE OIL</b> (UNII: U27K0H1H2O)			
	<b>TEA TREE OIL</b> (UNII: VIF565UC2G)			
	<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)			
	<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)			
	<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)			
	<b>CRYPTOCARYA AGATHOPHYLLA LEAF OIL</b> (UNII: XM00Z00H98)			
	<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)			
	<b>GINGER</b> (UNII: C5529G5JPQ)			
	<b>CASTOR OIL</b> (UNII: D5340Y2I9G)			
	<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)			
	<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)			
	<b>SESAME OIL</b> (UNII: QX10HYY4QV)			
<b>Packaging</b>				
#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70722-229-05	14 g in 1 CONTAINER; Type 0: Not a Combination Product	10/02/2016	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part348	10/02/2016		

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

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

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Little Moon Essentials		840835115	manufacture(70722-229)