

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.

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 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 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*)

organica olive oil (*olea europaea*)

organic ginger powder (*zingiber officinale*)

organic castor oil (*ricinus communis*)

beeswax (*cera alba*)

eucalyptus staigeriana

tea tree oil (*melaleuca alternifolia*)

wintegreen oil (*gaultheria procumbens*)

eucalyptus globulus oil

lemongrass oil (*cymbopogon citratus*)

lavender oil (*lavandula angustifolia*)

nutmeg oil (*myristica fragrans*)

ravensara oil (*rvensara aromatic*)

sage oil (*salvia officinalis*)

Principle Display Panel 113g container

<h3>Drug Facts</h3> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Camphor 0.6%.....</td> <td>Topical analgesic</td> </tr> <tr> <td>Menthol 5.2%.....</td> <td>Topical analgesic</td> </tr> </tbody> </table> <p>Uses temporarily relieves minor pain associated with ■ simple backache ■ muscle strains ■ sprains ■ bruises →</p>		Active Ingredients	Purpose	Camphor 0.6%.....	Topical analgesic	Menthol 5.2%.....	Topical analgesic	 <h1>VITAL VAPOR BALM™</h1> <p>PETROLEUM-FREE TOPICAL ANALGESIC</p> <p>LOT: (113)G NIP: 370792-274-04</p>	<h3>IT'S THE BALM</h3> <p>VITAL VAPOR BALM™ IS A STRONG, NATURAL ALTERNATIVE TO ARTIFICIAL, PETROLEUM BASED VAPOR RUB AND CAN BE USED IN MANY WAYS. THIS ALL-PURPOSE TOPICAL ANALGESIC CAN BE APPLIED TO SOOTHING AND OPEN YOUR LUNGS TO HELP OPEN NASAL PASSAGES. NATURALLY VITAL VAPOR BALM™ ALSO HELPS SOOTHE HEADACHES, SORE MUSCLES AND EVEN BUG BITES. A BETTER BALM FOR WHAT AILS YOU!</p> <p>DIRECTIONS: MASSAGE A THIN LAYER ONTO YOUR CHEST AND THROAT, OR SORE MUSCLES. RUB SMALL AMOUNT UNDER YOUR NOSE TO HELP OPEN NASAL PASSAGES. REPEAT AS NECESSARY BUT NO MORE THAN 3-4 TIMES DAILY, ALLOWING A MINIMUM OF 2-3 HOURS BETWEEN APPLICATIONS.</p> <p>WARNING: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES.</p>	 <p>6 73673 88218 3</p> <p>PO BOX 9789 • STEAMBOAT SPRING, CO 80477 TOLL FREE 888.272.6683 • WWW.LITTLEMOONESSENTIALS.COM LITTLE MOON ESSENTIALS™ VITAL VAPOR BALM™ REG. U.S. PAT. & TM. OFF.</p>
Active Ingredients	Purpose									
Camphor 0.6%.....	Topical analgesic									
Menthol 5.2%.....	Topical analgesic									
<p>HANDMADE IN COLORADO BY LITTLE MOON ESSENTIALS™ PLANET FRIENDLY • PLEASE REUSE OR RECYCLE 100% NATURAL INGREDIENTS • CRUELTY FREE</p>										

← PRESS WEB DIRECTION

Label:573123back Date:9/22/2016 Time:12:25:12

<h3>Drug Facts (continued)</h3> <p>Uses temporarily relieves minor pain associated with ■ simple backache ■ muscle strains ■ sprains ■ bruises</p>		<p>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</p> <p>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.</p>
<p>Warnings For external use only</p> <p>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 →</p>	<p>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 →</p>	

← PRESS WEB DIRECTION

Drug Facts (continued)**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).

← PRESS WEB DIRECTION

VITAL VAPOR

camphor, menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70722-229
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	0.6 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	5.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
CASTOR OIL (UNII: D5340Y2I9G)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SAGE OIL (UNII: U27K0H1H2O)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
NUTMEG OIL (UNII: Z1CLM48948)	

YELLOW WAX (UNII: 2ZA36H0S2V)

TEA TREE OIL (UNII: VIF565UC2G)

SESAME OIL (UNII: QX10HYY4QV)

CRYPTOCARYA AGATHOPHYLLA LEAF OIL (UNII: XM00Z00H98)

GINGER (UNII: C5529G5JPQ)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-229-04	113 g in 1 CONTAINER; Type 0: Not a Combination Product	10/02/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/02/2016	

Labeler - Little Moon Essentials (840835115)

Registrant - Little Moon Essentials LLC (840835115)

Establishment

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

Revised: 12/2020

Little Moon Essentials