

CRAMPY BELLY RUB- camphor oil

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 Ingredient

Camphor 1.1%

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 or mucous membranes
- ☐Do not apply to wounds or damaged, broken or irritated skin
- ☐A transient burning sensation may occur upon applications 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 3 to 4 times daily, allowing a minimum of 2-3 hours between applications
- **AFTER APPLYING, WASH HAND WITH SOAP AND WATER**

children 12 years or younger: ask a doctor

Other information

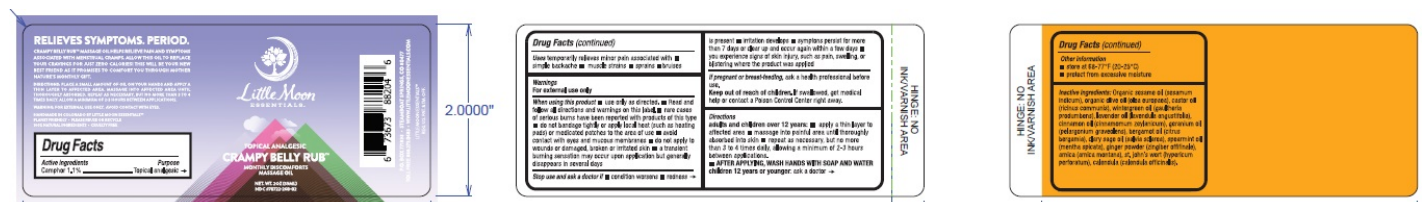
Store at 68-77°F (20-25°C)

Protect from excessive moisture

Inactive Ingredients

- Organic Sesame oil (Sesamum indicum)
- Organic Olive oil (Olea Europaea)
- Castor oil (Ricinus communis)
- Wintergreen oil (Gaultheria procumbens)
- Lavender oil (Lavendula angustifolia)
- Cinnamon oil (Cinnamomum zeylanicum)
- Geranium oil (Pelargonium graveolens)
- Bergamot oil (Citrus bergamia)
- Clary sage oil (Salvia sclarea)
- Spearmint oil (Mentha spicata)
- Ginger powder (Zingiber officinale)
- Arnica (Arnica Montana)
- st. john's wort (Hypericum perforatum)
- Calendula (Calendula officinalis)

Principle Display Panel - 2 oz Bottle



CRAMPY BELLY RUB

camphor oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70722-260
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	1.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SESAME OIL (UNII: QX10HYY4QV)	
CASTOR OIL (UNII: D5340Y2I9G)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
BERGAMOT OIL (UNII: 39W1PKE3J1)	
GINGER OIL (UNII: SAS9Z1SVUK)	
ARNICA MONTANA (UNII: O80TY208ZW)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
SPEARMINT OIL (UNII: C3M81465G5)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-260-02	56.7 g in 1 BOTTLE; 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 monograph not final	part348	09/28/2016	

Labeler - Little Moon Essentials (840835115)

Registrant - Little Moon Essentials LLC (840835115)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Little Moon Essentials LLC

840835115

manufacture(70722-260)

Revised: 12/2020

Little Moon Essentials