

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 Ingredients

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 on serious burn 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 wound 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

- Conditions worsens
- 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 were 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 thin layer to affected area
- Massage into painful area until thoroughly absorbed into skin
- Repeat as necessary, but no more than 3 to 4 time 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

Organis Sesame oil (Sesamum indicum)

Organic Olive oil (Olea Europea)

Castor oil (Ricinus communis)

Wintergreen oil (Gaultheria procumbens)

Lavender oil (Lavendula angustifolia)

Cinnamom oil (Cinnamomum zeylanicum)

Geranium oil (Pelargonium graveolens)

Bergamot oil (Citrus bergamia)

Clary sage oil (Salvia sclarea)

Spearmint oil (mentha spicata)

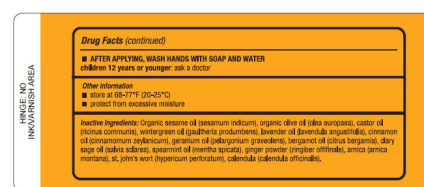
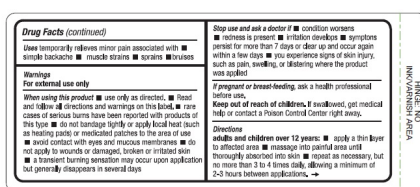
Ginger powder (Zingiber officinale)

Arnica (Arnica Montana)

st. john's wort (Hypericum perforatum)

Calendula (calendula officinalis)

Principle Display Panel - 4 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)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
BERGAMOT OIL (UNII: 39W1PKE3JI)	
SPEARMINT OIL (UNII: C3M81465G5)	
GINGER (UNII: C5529G5JPO)	
ARNICA MONTANA (UNII: O80TY208ZW)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CASTOR OIL (UNII: D5340Y2I9G)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-260-04	113.4 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)

