

ASANA KISSER- camphor, menthol cream

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 1.35%

Menthol 2.86%

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 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 :

- Applying 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 Cayenne powder (Capsicum frutescens)

Organic ginger powder (Zingiber officinalis)

Organic Castor oil (Ricinus communis)

Beeswax (Cera alba)

Wintergreen oil (Gaultheria Procumbens)

Rosemary oil (Rosmarinus officinalis)

Cinnamon oil (Cinnamomum zeylanicum)

Lavender oil (Lavandula angustifolia)

Clary sage (Salvia sclarea)

Geranium oil (Pelargonium graveolens)

Ginger oil (Zingiber officinale)

Basil oil (Ocimum basilicum)

Marjoram (Thymus mastichina)

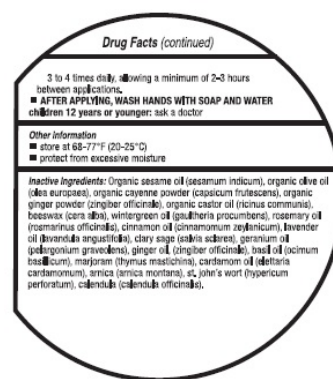
Cardamon oil (Elettaria cardamomum)

Arnica (Arnica Montana)

St. John's wort (Hypericum perforatum)

Calendula (Calendula officinalis)

Principle Display Panel 85.05g container



ASANA KISSER

camphor, menthol cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70722-216 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------------|-----------------|
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 2.86 g in 100 g |
| CAMPBOR (NATURAL) (UNII: N20HL7Q941) (CAMPBOR (NATURAL) - UNII:N20HL7Q941) | CAMPBOR (NATURAL) | 1.35 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------------------|----------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |

| | |
|--|--|
| CINNAMON OIL (UNII: E5GY4I6YCZ) | |
| SESAME OIL (UNII: QX10HYY4QV) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| RED PEPPER (UNII: 6M47G7C4SY) | |
| GINGER (UNII: C5529G5JPQ) | |
| CASTOR OIL (UNII: D5340Y2I9G) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| ROSEMARY OIL (UNII: 8LGU7VM393) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| CLARY SAGE (UNII: U3HSK5JC0Q) | |
| GINGER OIL (UNII: SAS9Z1SVUK) | |
| BASIL OIL (UNII: Z129UMU8LE) | |
| SWEET MARJORAM (UNII: G9Z40ZYU6P) | |
| CARDAMOM OIL (UNII: JM0KJ091HZ) | |
| HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG) | |
| ARNICA MONTANA (UNII: O80TY208ZW) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70722-216-03 | 85.05 g in 1 CONTAINER; Type 0: Not a Combination Product | 09/30/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 09/30/2016 | |

Labeler - Little Moon Essentials (840835115)

Registrant - Little Moon Essentials LLC (840835115)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Little Moon Essentials LLC | | 840835115 | manufacture(70722-216) |