

ASS 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 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 blister 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 child 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 Cayenne powder (*Capsicum frutescens*)

Organic Ginger powder (*Zingiber officinale*)

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 officinales*)

Basil oil (*Ocimum basilicum*)

Marjoram (*Thymus mastichina*)

Arnica (*Arnica Montana*)

st. john's wort (*Hypericum perforatum*)

Calendula (*Calendula officinalis*)

Principle Display Panel- 85.05g Container



ASS KISSER

camphor, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70722-208
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	

OLIVE OIL (UNII: 6UYK2W1W1E)
CASTOR OIL (UNII: D5340Y2I9G)
RED PEPPER (UNII: 6M47G7C4SY)
GINGER (UNII: C5529G5JPQ)
METHYL SALICYLATE (UNII: LAV5U5022Y)
ROSEMARY OIL (UNII: 8LGU7VM393)
LAVENDER OIL (UNII: ZBP1YXW0H8)
GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)
GINGER OIL (UNII: SAS9Z1SVUK)
SWEET MARJORAM (UNII: G9Z40ZYU6P)
CARDAMOM OIL (UNII: JM0KJ091HZ)
ARNICA MONTANA (UNII: O80TY208ZW)
CLARY SAGE (UNII: U3HSK5JC0Q)
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
SESAME OIL (UNII: QX10HYY4QV)
CINNAMON OIL (UNII: E5GY4I6YCZ)
BASIL OIL (UNII: Z129UMU8LE)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-208-03	85.05 g in 1 CONTAINER; Type 0: Not a Combination Product	09/29/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/29/2016	

Labeler - Little Moon Essentials (840835115)

Registrant - Little Moon Essentials LLC (840835115)

Establishment			
Name	Address	ID/FEI	Business Operations
Little Moon Essentials LLC		840835115	manufacture(70722-208)