

MAGICAL MUSCLE OIL- camphor, menthol 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 1.95%

Menthol 3.75%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor in 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 of this label
- Rare cases of 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 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

- Conditions 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)

Organic Olive oil (Olea Europaea)

Organic Cayenne Powder (Capsicum Frutescens)

Organic Ginger powder (Zingiber Officinale)

Organic Castor oil (Ricinus Communis)

Wintergreen oil (Gaultheria Procumbens)

Cinnamon oil (Cinnamomum zeylanicum)

Lavender oil (Lavendula Angustifolia)

Clary sage oil (Salvia sclarea)

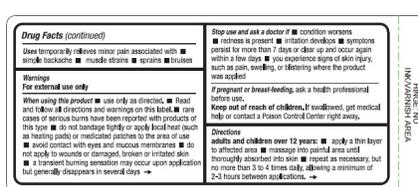
Marjoram oil (Thymus mastichina)

Basil oil (Ocimum basilicum)

Cardamon oil (Elettaria cardamomum)

Ginger oil (Zingiber officinale)

Principal Display Panel- 4 oz (118ml) bottle



MAGICAL MUSCLE OIL

camphor, menthol oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70722-246
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.75 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	1.95 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
GINGER (UNII: C5529G5JPQ)	
CASTOR OIL (UNII: D5340Y2I9G)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
RED PEPPER (UNII: 6M47G7C4SY)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SWEET MARJORAM OIL (UNII: ICH7BE016E)	
BASIL OIL (UNII: Z129UMU8LE)	
CARDAMOM OIL (UNII: JM0KJ091HZ)	
SESAME OIL (UNII: QX10HYY4QV)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
GINGER OIL (UNII: SAS9Z1SVUK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70722-246-04	113.4 g in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/27/2016	

Labeler - Little Moon Essentials (840835115)

Registrant - Little Moon Essentials LLC (840835115)

Establishment

Name	Address	ID/FEI	Business Operations
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Little Moon Essentials LLC

840835115

manufacture(70722-246)

Revised: 12/2020

Little Moon Essentials