# ACHING HEAD RUB- camphor, menthol ointment 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.

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#### **Active Ingredients**

Camphor 3.09%

Menthol 2.55%

#### **Purpose**

Topical Analgesic

#### Uses

temporarily relieves minor pain associated with

- Isimple 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 no 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 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 blistering where the product was applied

#### If pregnant or breastfeeding

ask a health professional before use

#### **Directions**

Adults and children over 12 years

- Apply a thin layer to affected area
- Massage into painful area until throughly absorbed into skin
- Repeat as necessary, but no more than 3 to 4 times daily, allowing a minimum of 2-3 hours bewteen applications.
- AFTER APPLYING, WASH HANDS WITH SOAP AND WATER

#### Children 12 years or younger: ask a doctor

#### Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

#### **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 ginger powder (zingiber officinale)

organic castor oil (ricinus communis)

beeswax (cera alba)

wintergreen oil (gaultheria procumbens)

marjoram (thymus mastichina)

cinnamon oil (cinnamomum zeylanicum)

lavender oil (lavandula angustifolia)

eucalyptus globulus

clary sage (salvia sclarea)

rosemary oil (rosmarinus officinalis)

basil oil (ocimum basillicum)

peppermint oil (menthe piperita)

### Principle Display Panel-28g Container

HANDMADE IN COLORADO BY LITTLE MOON ESSENTIALS\*\*
PLANET FRIENDLY • PLEASE REUSE OR RECYCLE



PO. BOX 771893 - STEAMBOAT SPRINGS, CO 80477 FOLL FREE 888.2731.0683 - WWW.LITILEMOONESSENTIALS.COM. LITTLE MOON ESSENTIALS\*\* ACHING HEAD RUB!\*\* PEG U.S. PAT. 8 TM. OFF:



## ACHING HEAD RUB<sup>\*</sup>

ALL-NATURAL TOPICAL ANALGESIC

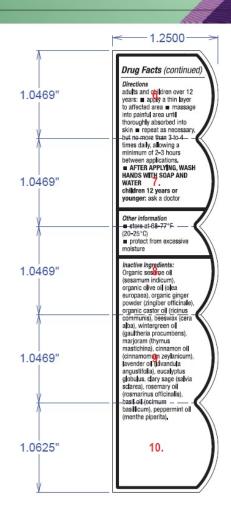
#### GET A-HEAD OF THE GAME

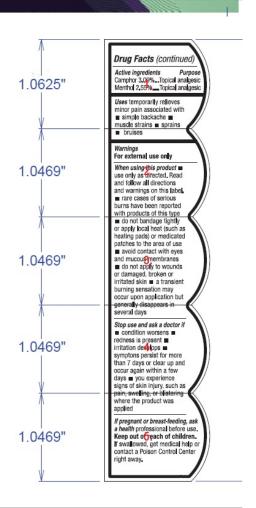
ACHING HEAD RUB" IS A STRONG AROMATIC SAIVE THE SOOTHES SERIOUS HEADACHE PAIN. THE MENTHOL HELL PROVIDE A COOLING RELIEF AND THE ESSENTIAL OILS LAV PROBEAMDMA.RIDBAM ARE SPECIFIC REMEDIES FOR TYPES OF HEADACHES AND STRESS, RUB YOUR HEADACH ANAY, NATURALLY.

DIRECTIONS: MASSAGE A THIN LAYER ONTO YOUR TEMPLES.
MECK AND SHOULDERS UNTIL THOROUGHLY ABSORBEE
INTO SKIN REPEAT AS NECESSARY BUT NO MORE THAN 3 TO
4 TIMES DAILY, ABLOWING A MINIMUM OF 2-3 HOURS
BETWEEN APPLICATIONS.

VARNING FOR EXTERNAL USE ONLY, AVOID CONTACT WITH EYES







#### ACHING HEAD RUB

camphor, menthol ointment

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70722-203

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENT UNII:L7T10EIP3A)	HOL, UNSPECIFIED FORM -	MENTHOL, UNSPECIFIED FORM	2.55 g in 100 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NAUNII:N20HL7Q941)	TURAL) -	CAMPHOR (NATURAL)	3.09 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
GINGER (UNII: C5529G5JPQ)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
SWEET MARJORAM (UNII: G9Z40ZYU6P)	
CINNAMON OIL (UNII: E5GY4I6 YCZ)	
CLARY SAGE OIL (UNII: 87L0 D4U3M0)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
BASIL OIL (UNII: Z129 UMU8 LE)	
SESAME O IL (UNII: QX10 HYY4QV)	
CASTOR OIL (UNII: D5340 Y219 G)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:70722-203-	28 g in 1 CONTAINER; Type 0: Not a Combination Product	09/28/2016	
1 NDC./0/22-203-	71 20 g in 1 GONTAINER, Type 0. Not a Combination Floudet	03/20/2010	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	09/26/2016		

## Labeler - Little Moon Essentials (840835115)

## Registrant - Little Moon Essentials LLC (840835115)

Establishment				
Name	Address	ID/FEI	Business Operations	
Little Moon Essentials LLC		840835115	manufacture(70722-203)	

Revised: 12/2020 Little Moon Essentials