TOP MEDICATED PAIN RELIEVING- camphor, menthol, methyl salicylate oil Albert Max, Inc.

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.

TOP MEDICATED OIL

Drug Facts

Active ingredients

Camphor 10%

Menthol 16%

Methyl Salicylate 40%

Purpose

External Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

• simple backache • arthritis • strains • bruises • sprains

Warnings

For external use only

Do not use

- on wounds
- on irritated or damaged skin
- otherwise than as directed

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive irritation of the skin develops
- nausea, vomiting, abdominal discomfort, diarrhea, or skin rashes occurs

Keep out of reach of children

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

Directions

- adults and children 12 years of age and older: apply 3 to 4 drops of medicated oil to the affected area 1 to 2 times daily. After applying the product, a warm pad may be placed on the affected area for 10 minutes and then massage as shown in the illustrations.
- children under 12 years of age: consult your physician.
- refer to the above warnings; use otherwise than as directed may be dangerous.

Other information

• store at 16° to 30°C (61° to 86° F) • store in an airtight container

Inactive ingredients

• Eucalyptus oil • Lavender oil

DISTRIBUTED BY:

A&A MEDICAL SUPPLIES, INC. S. El Monte, CA 91733 USA MADE IN TAIWAN ITEM NO. HK105

Packaging



DRUG FACTS LABEL



camphor, menthol, methyl salicylate oil

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68233-808 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|---------------------------|-------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CAMPHOR (NATURAL) (UNII: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII:N20 HL7Q941) | CAMPHOR (NATURAL) | 0.1 g in 1 mL | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 0.16 g in 1 mL | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 0.4 g in 1 mL | |

| Inactive Ingredients | | | |
|-----------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | | | |
| LAVENDER O IL (UNII: ZBP1YXW0H8) | | | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|--|
| Color | yello w | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | | |
|-----------|-----|------------------|--|-----------------------------|--------------------|
| ı | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 N | NDC:68233-808-01 | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/24/2012 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part348 | 05/24/2012 | |
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Labeler - Albert Max, Inc. (149445798)

Revised: 12/2018 Albert Max, Inc.