

AXE BRAND MEDICATED- menthol, camphor and methyl salicylate oil
LEUNG KAI FOOK MEDICAL CO PTE LTD

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

Menthol 16%

Camphor 5%

Methyl salicylate 15%

Purpose

External analgesic

Uses

For the temporary relief of 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

on the face

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 rash occurs

when using for pain of arthritis

pain persists for more than 10 days

redness is present

in conditions affecting children under 12 years of age

Keep out of reach of children to avoid accidental poisoning
If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 3 years of age and older: Apply a few drops then gently rub into the affected area not more than 3 to 4 times daily.

Children under 3 years of age: Do not use, consult your doctor.

Refer to the above warnings; use otherwise than as directed may be dangerous

Other information

keep container tightly closed

store at 15 to 30C (59 to 86F)

Inactive ingredients

Eucalyptus oil, lavender oil and mineral oil.

Questions or comments? (888)221-3496 M-F 9am to 5pm
you may also report serious side effects to this phone number

AXE BRAND MEDICATED OIL NDC-57538-003-1 1.89 fl oz (56mL)



External Analgesic NDC 57538-003-01



AXE BRAND MEDICATED OIL

- ✓ Simple Backache
- ✓ Arthritis
- ✓ Strains
- ✓ Bruises
- ✓ Sprains

全美總代理：
Sole Agent of U.S.A.,
Canada, & South America:
 SOLSTICE MEDICINE COMPANY
215 W. Ann Street
Los Angeles, CA 90012
Toll Free:
1-888-221-3496
WWW.SOLSTICEMED.COM
1.89 FL OZ (56 ML)

Drug Facts

Active Ingredients:

| | |
|-----------------------------|--------------------|
| Menthol 16% | Purpose: |
| Camphor 5% | External Analgesic |
| Methyl salicylate 15% | External Analgesic |

Uses: For the temporary relief of 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 • on the face • 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 develop or worsen after a few days • excessive irritation of the skin develops • nausea, vomiting, abdominal discomfort, dizziness, or skin rash occurs • when using for pain of arthritis.



No.1 壹號
斧標驅風油
居家旅行 常備良藥
新加坡 梁介福藥業私人有限公司
1.89 液盎司 (56 毫升)

Drug Facts (Continued)

- pain persists for more than 10 days
- redness is present
- in children, affecting children under 12 years of age

Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: • adults and children 3 years of age and older: Apply a few drops, then gently rub into the affected area not more than 3-4 times daily. • children under 3 years of age: Do not use, consult your physician.

• refer to the above warning, use otherwise than as directed may be dangerous.

Other Information: • keep container tightly closed • store below 30°C (86°F)

Inactive Ingredients: Eucalyptus oil, Lavender oil, and Mineral oil.

Questions or Comments? (888) 221-3496
M-F, 9 am to 5 pm
• you may also report serious side effects to the phone number.

Manufactured by: **Leung Kai Fook Medical Co Pte Ltd**
Singapore 368238 Made in Singapore

Lot No.



AXE BRAND MEDICATED
menthol, camphor and methyl salicylate oil

| Product Information | | | | |
|--|------------------|---|----------------------|--------------------|
| Product Type | | HUMAN OTC DRUG | Item Code (Source) | |
| Route of Administration | | TOPICAL | NDC:57538-003 | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A) | | | MENTHOL | 16 g in 100 mL |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | | | CAMPHOR (SYNTHETIC) | 5 g in 100 mL |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | | | METHYL SALICYLATE | 15 g in 100 mL |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | | | | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | | | | |
| MINERAL OIL (UNII: T5L8T28FGP) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:57538-003-01 | 56 mL in 1 PACKAGE; Type 0: Not a Combination Product | 04/13/2001 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part348 | 04/13/2001 | |

Labeler - LEUNG KAIFOOK MEDICAL CO PTE LTD (595107004)

| Establishment | | | |
|----------------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| LEUNG KAIFOOK MEDICAL CO PTE LTD | | 595107004 | manufacture(57538-003) |