

HUO LUO PAIN RELIEVING- camphor, menthol, methyl salicylate oil
MADISON ONE ACME 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.

Drug Facts

Active ingredients

Camphor 10%

Menthol 16%

Methyl salicylate 50%

Purpose

External analgesic

External analgesic

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

Ask a doctor or pharmacist before use if you have

- any concerns about using this product

When using this product

- do not use otherwise than as directed
- avoid contact with the eyes or mucous membranes
- ☐■ do not bandage tightly
- ☐■ do not apply heat to the area in the form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns)

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
- you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation)
- 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

Report any unexpected side effects from the use of this product to the FDA MedWatch Program

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 several drops and rub into the affected area not more than 3 to 4 times daily
- children under 3 years of age: consult your physician

Other information

- keep container tightly closed
- store protected from light at 15 to 30 C (59 to 86 F)

Inactive ingredients

Angelica biserrata root, angelica sinensis root, arisaema erubescens root, chaenomeles lagenaria fruit, cinnamomum cassia twig, clematis chinensis root, cyathula officinalis root, dragon's blood, eleutherococcus nodiflorus root bark, illicium difengpi bark, lavandula angustifolia subsp. angustifolia whole, light mineral oil, ligusticum sinense subsp. chuanxiong root, narcissus jonquilla flower oil, notopterygium franchetii root, and sigesbeckia orientalis flowering top.

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

- you may also report serious side effects to this phone number

HUO LUO PAIN RELIEVING OIL

NDC 55614-671-01

EXTERNAL ANALGESIC

1.69 FL OZ (50 ML)

活絡油 紙盒

Huo Luo Pain Relieving Oil 50mL Box

Size: 53 (W) x 27.5 (D) x 140.5 (H) mm

12/16/2020



Drug Facts (Continued) 藥品資料 (續)
 and ingredients in the following top:
 藥效、藥劑、藥性、不潔、材料、藥用山、牛黃、珍珠、五倍、地膚皮、藥油
 藥效、藥劑、藥性、不潔、材料、藥用山、牛黃、珍珠、五倍、地膚皮、藥油
 Questions or comments? 問題或意見? (888) 221-3496
 If 8 am to 5 pm, Monday-Friday, call our toll-free number.
 您可向本藥廠查詢有關詳情。

Drug Facts 藥品資料
Active ingredients 有效成份 Purpose 用途
 Camphor 樟腦 10%.....External analgesic 外傷止痛藥
 Methyl salicylate 18%.....External analgesic 外傷止痛藥
 Methyl salicylate 50%.....External analgesic 外傷止痛藥
 水楊酸甲酯
Uses 作用
 For the temporary relief of minor aches and pains of muscles and joints due to:
 暫時緩解以下症狀引起的肌肉和關節疼痛：
 ■ simple backache 一般腰背痛 ■ arthritis 關節炎
 ■ strains 扭傷 ■ bruises 瘀傷 ■ sprains 扭傷
Warnings 警告
 For external use only 本品僅供外用
 Do not use 不要用於
 ■ on wounds 傷口
 ■ on irritated or damaged skin 過敏或破損的皮膚
 Ask a doctor or pharmacist before use if you have
 如果有以下情況，在使用前請先諮詢醫生或藥劑師
 ■ any concerns about using this product
 對使用本產品有任何疑慮
 When using this product 在使用本品時
 ■ do not use otherwise than as directed 請遵照醫藥使用
 ■ avoid contact with the eyes or mucous membranes
 避免接觸眼睛或黏膜
 ■ do not bandage tightly 切勿貼過緊
 ■ do not apply heat to the area in the form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns)
 不要以加熱墊、熱水袋或加熱燈的形式對患處施加熱量（這樣做會增加嚴重灼傷的風險）
Stop use and ask a doctor if
 如果出現下列情況應停止使用本品並諮詢醫生
 ■ condition worsens 情況加重
 ■ symptoms persist for more than 7 days
 症狀持續七天以上
 ■ symptoms clear up and occur again within a few days
 症狀消失幾天後又再出現
 ■ excessive irritation for the skin develops 皮膚出現過敏、
 nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs
 噁心、嘔吐、腹瀉不適、腹瀉或出現皮疹
 ■ you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation) 使用後您感到實際疼痛或起水泡或灼傷（感覺溫暖或涼快是正常的）
 ■ when using for pain of arthritis 用於關節炎止痛時：
 ■ pain persists for more than 10 days
 疼痛持續超過十天
 ■ redness is present 皮膚發紅
 ■ in conditions affecting children under 12 years of age
 影響12歲以下兒童的症狀
Report any unexpected side effects from the use of this product to the FDA MedWatch Program
 向 FDA MedWatch 計劃報告使用本產品所產生的任何意外副作用
 Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a

Drug Facts (Continued) 藥品資料 (續)
Directions 用法
 Rub a small amount of the oil on the affected area 3 or 4 times a day.
 每天塗抹少量油於患處3或4次。
Other information 其他資訊
 Contains 1.69 FL. OZ. (50 mL) of product.
 含有1.69 液量盎司 (50 毫升) 產品。

Drug Facts (Continued) 藥品資料 (續)
Inactive ingredients 非活性成分
 Alpha bisabolol, arnica montana, benzoin resin, camphor, clove oil, eucalyptus oil, geraniol, ginger oil, lavender oil, lemon balm oil, menthol, peppermint oil, rosemary oil, sandalwood oil, tea tree oil, wintergreen oil, ylang-ylang oil, and other natural oils.
 亞細亞百里香醇、洋甘菊、乳香樹脂、樟腦、丁香油、桉樹油、香茅油、薑油、薰衣草油、檸檬香茅油、薄荷、薄荷油、迷迭香油、檀香油、茶樹油、冬青油、依蘭油和其他天然油類。

NDC 55614-671-01

HUO LUO OIL
PAIN RELIEVING OIL
 External Analgesic

活絡油
 跌打聖藥 風濕特效

1.69 FL. OZ (50mL) (毫升)

U.S. Distributor 美國總代理
SUN SHINE MEDICINE COMPANY
 美國林氏藥業有限公司
 215 W. Ann St., Los Angeles, CA 90012
 Toll Free: 1-888-221-3496
 www.sunshinemedicine.com
 800-671-0114



camphor, menthol, methyl salicylate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-671
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	16 g in 100 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	50 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ANGELICA BISERRATA ROOT (UNII: OJ90180B22)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
ARISAEMA ERUBESCENS ROOT (UNII: 3E8P1PU8SY)	
CHAENOMELES LAGENARIA FRUIT (UNII: XBC17A15MU)	
CINNAMOMUM CASSIA TWIG (UNII: 4UD6VQR2UP)	
CLEMATIS CHINENSIS ROOT (UNII: 8Z18N528CU)	
CYATHULA OFFICINALIS ROOT (UNII: BRM37UP34O)	
DRAGON'S BLOOD (UNII: M3YJ2C28IC)	
ELEUTHEROCOCCUS NODIFLORUS ROOT BARK (UNII: W7PRK433YB)	
ILLICIAM DIFENGPI BARK (UNII: JRF2FQL2SB)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA WHOLE (UNII: 51217XIL5L)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
LIGUSTICUM SINENSE SUBSP. CHUANXIONG ROOT (UNII: RR83T99U97)	
NARCISSUS JONQUILLA FLOWER OIL (UNII: QJD826L75Z)	
INCISED NOTOPTERYGIUM RHIZOME OR ROOT (NOTOPTERYGIUM FRANCHETII) (UNII: KRT28P6ITK)	
SIGESBECKIA ORIENTALIS FLOWERING TOP (UNII: 6UL878YAR7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-671-01	1 in 1 BOX	12/18/2020	
1		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/18/2020	

Labeler - MADISON ONE ACME INC (096196758)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-671)

Revised: 12/2020

MADISON ONE ACME INC