

E MEI SHAN MEDICATED- camphor, menthol plaster
Zhejiang Dingtai Pharmaceutical Co., 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

Camphor 3.1%

Menthol 2.6%

Purpose

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

Allergy alert: This product contains natural rubber latex which may cause allergic reactions

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

Do not use

- on irritated or damaged skin
- on wounds

Ask a doctor or pharmacist before use if you have

- any concerns about using this product

When using this product

- 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)
- avoid placing on extremely hairy areas of skin to avoid irritation upon removing the plaster

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

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

Directions

- adults and children 2 years of age and older: remove the protective film from the plaster. Apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult your physician

Other information

- keep plasters tightly closed in the zip-lock pouch
- store at 15° to 30° C (59° to 86° F) in a dry place away from sunlight

Inactive ingredients

Butylated hydroxytoluene, dong quai root, fragrant angelica root, ginger root, lanolin, light mineral oil, natural latex rubber, petrolatum, rosin, star anise fruit, and zinc oxide on a cotton pad

Questions or comments?

(888) 221-3496 M-F 9 am to 5 pm

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

E MEI SHAN MEDICATED PLASTER

NDC 69070-300-01

Simple backache, Arthritis, Strains, Bruises, Sprains

5 Plaster

Each Plaster 7 x 10 cm (2.76 x 3.94 in)

Drug Facts 藥品資料

Active Ingredients 有效成份
Camphor 樟腦 3.1% External Analgesic 外用止痛
Menthol 薄荷腦 2.0% External Analgesic 外用止痛

Purpose 用途

Uses 作用 For the temporary relief of minor aches and pains of muscles and joints due to: 暫時緩解以下情況引起的肌肉和關節疼痛:
■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains
■ 背痛 ■ 關節炎 ■ 扭傷 ■ 瘀傷 ■ 挫傷

Warnings 警告 For external use only 只限外用
Allergy alert 過敏警告: This product contains natural rubber latex which may cause allergic reactions. 本品含有天然橡膠乳膠，可能引起過敏反應。

Do not use 不應用於
■ on irritated or damaged skin 發炎或破損皮膚 ■ on wounds 傷口
Ask a doctor or pharmacist before use if you have
■ any concerns about using this product 對使用本品有任何疑慮

When using this product 在使用本品時
■ avoid contact with the eyes or mucous membranes 避免接觸眼睛或黏膜
■ do not bandage tightly 勿包緊過緊
■ 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) 不要在加熱墊、熱水瓶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)
■ avoid placing on extremely hairy areas of skin to avoid irritation upon removing the plaster 避免貼在毛髮濃密處，以免在撕掉膏藥時引起皮膚發炎

Stop use and ask a doctor if 立即停止使用並向醫生諮詢，如果
■ condition worsens 病情惡化
■ 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 症狀好轉幾天後又復發
■ excessive irritation of the skin develops 皮膚有嚴重刺激或發炎
■ 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) 在貼藥後你感覺到實質的疼痛或出現非此藥所有的熱感 (溫暖或清涼的感覺是正常的)
■ when using for pain of arthritis 用於治療關節炎引起的疼痛時:
■ pain persists for more than 10 days 疼痛持續超過10天
■ itches or is present 發癢
■ in conditions affecting children under 12 years of age 影響12歲以下兒童的情況

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

Drug Facts 藥品資料 (continued) 續

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 放置於兒童接觸不到的地方。如果被吞食，請立即聯繫醫療服務控制中心。

Directions 使用說明
■ adults and children 2 years of age and older: remove the protective film from the plaster. Apply to affected areas not more than 3 to 4 times daily. 成人及2歲以上兒童：從膏藥上取下保護膜。貼於患處，每日不超過3至4次。
■ children under 2 years of age: consult your physician 2歲以下兒童：向醫生諮詢

Other information 其他資訊
■ keep plasters tightly closed in the zip-back pouch 將膏藥密封保存於拉鍊袋中
■ store at 15° to 30°C (59° to 86°F) in a dry place away from sunlight 在攝氏15°至30° (華氏59°至86°) 下保存於乾燥避光之處

Inactive ingredients 非活性成分
Butylated hydroxytoluene, dong quai root, fragrant angelica root, ginger root, lanolin, light mineral oil, natural latex rubber, petrolatum, rosin, star anise fruit, and zinc oxide on a cotton pad 二丁基羥基甲苯、當歸、白芷、干薑、羊毛脂、輕質礦油石蠟、天然橡膠、黃凡士林、松香、八角茴香、氧化鋅

Questions or comments? 問題或意見? (888) 221-3486
M-F 9 am to 5 pm 週一至週五，上午9時至下午5時
■ you may also report serious side effects to this phone number.
您還可以使用這個電話號碼報告嚴重的副作用

製造商 Manufacturer By:
浙江鼎泰藥業股份有限公司
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ZHEJIANG 314500, CHINA
美國總代理 U.S. Distributor:
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美國蘇氏藥業有限公司
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www.solsticemed.com
Product of China 中國產品 Lot No. Exp. Date.

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Pantone
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峨嵋山風濕膏

SOLSTICE MEDICINE COMPANY

NDC 69070-300-01



民間秘方 療效顯著
精工提煉 使用方便

峨嵋山風濕膏

E MEI SHAN
MEDICATED PLASTER

※新劑型 ※新配方 ※可拉長或伸縮

- ✓ Simple backache 一般腰背痛
- ✓ Arthritis 關節炎
- ✓ Strains 損傷
- ✓ Bruises 瘀傷
- ✓ Sprains 扭傷

5 PLASTER (五貼裝) 每貼 (7厘米 x 10厘米)
Each Plaster 7 x 10 cm (2.76 x 3.94 in)

E MEI SHAN
MEDICATED PLASTER

峨嵋山牌

NEW PACKAGING STARTING SEPTEMBER 2018
自二零一八年九月改用此新裝

camphor, menthol plaster

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69070-300
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	31 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	26 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
GINGER (UNII: C5529G5JPQ)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
PETROLATUM (UNII: 4T6H12BN9U)	
ROSIN (UNII: 88S87KL877)	
STAR ANISE (UNII: XKC1657P78)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69070-300-01	1 in 1 BOX	09/17/2018	
1		5 in 1 POUCH; 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	09/17/2018	

Labeler - Zhejiang Dingtai Pharmaceutical Co., Ltd (420598724)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(69070-300)