

**ZANG HONG HUA PAIN RELIEVING- camphor, capsaicin, and 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.*

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**Drug Facts**

***Active ingredient***

Camphor 10%

Capsaicin 0.025% (from capsicum oleoresin)

Methyl salicylate 60%

***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 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**

■ 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*** cinnamon leaf oil, cinnamon oil, citronella oil, dragon's blood, light mineral oil, and saffron.

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

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

ZANG HONG HUA PAIN RELIEVING OIL

Camphor, Capsaicin, and Methyl salicylate

NDC 55614-641-01

EXTERNAL ANALGESIC

1.69 FL OZ (50 ML)

# 藏紅花油 紙盒

Zang Hong Hua Pain Relieving Oil 1.69FL OZ (50ML) Box

Size: 53 (W) x 28 (D) x 140.5 (H) mm

04/19/2021



## ZANG HONG HUA PAIN RELIEVING

camphor, capsaicin, and methyl salicylate oil

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55614-641

Route of Administration	TOPICAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	10 g in 100 mL
<b>CAPSAICIN</b> (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 mL
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	60 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>CINNAMON LEAF OIL</b> (UNII: S92U8SQ71V)	
<b>CINNAMON OIL</b> (UNII: E5GY4I6YCZ)	
<b>CITRONELLA OIL</b> (UNII: QY08Q067D0)	
<b>DRAGON'S BLOOD</b> (UNII: M3YJ2C28IC)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>SAFFRON</b> (UNII: E849G4X5YJ)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-641-01	1 in 1 BOX	03/30/2021	
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	03/30/2021	

**Labeler** - MADISON ONE ACME INC (096196758)**Establishment**

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-641)

Revised: 4/2021

MADISON ONE ACME INC