QIAN LI ZHUI FENG PAIN RELIEVING- camphor, menthol, 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.

Drug Listing

Active ingredients

Camphor 10% Menthol 15% Methyl salicylate 48%

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, chaenomeles lagenaria fruit, clematis chinensis root, corydalis yanhusuo tuber, gentiana macrophylla root, lavender oil, mineral oil, sinomenium acutum stem, and taxillus chinensis 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

QIAN LI ZHUI FENG PAIN RELIEVING OIL

NDC 55614-690-01

EXTERNAL ANALGESIC



QIAN LI ZHUI FENG PAIN RELIEVING

camphor, menthol, and methyl salicylate oil

Pro	duc	t Inf	orm	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55614-690

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	15 g in 100 mL		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:0414PZ4LPZ)	METHYL SALICYLATE	48 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
ANGELICA BISERRATA ROOT (UNII: OJ90180B22)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
CHAENOMELES LAGENARIA FRUIT (UNII: XBC17A15MU)	
CLEMATIS CHINENSIS ROOT (UNII: 8Z18N528CU)	
CORYDALIS YANHUSUO TUBER (UNII: 0TUP42692Z)	
GENTIANA MACROPHYLLA ROOT (UNII: 6559FC0U1B)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MINERAL OIL (UNII: T5L8T28FGP)	
SINOMENIUM ACUTUM STEM (UNII: BBH96IEM66)	
TAXILLUS CHINENSIS TOP (UNII: QJ523LD71P)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:55614- 690-01	1 in 1 BOX	10/27/2020	
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	10/27/2020		

Labeler - MADISON ONE ACME INC (096196758)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-690)	

Revised: 3/2021 MADISON ONE ACME INC