

**JOSEPHS LION PAIN RELIEVING- camphor, menthol, methyl salicylate oil  
MADISON ONE ACME INC**

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**Drug Facts**

***Active ingredient***

Camphor 5%  
Menthol 8%  
Methyl salicylate 10%

***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***

Anise oil, cajuput 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 this phone number

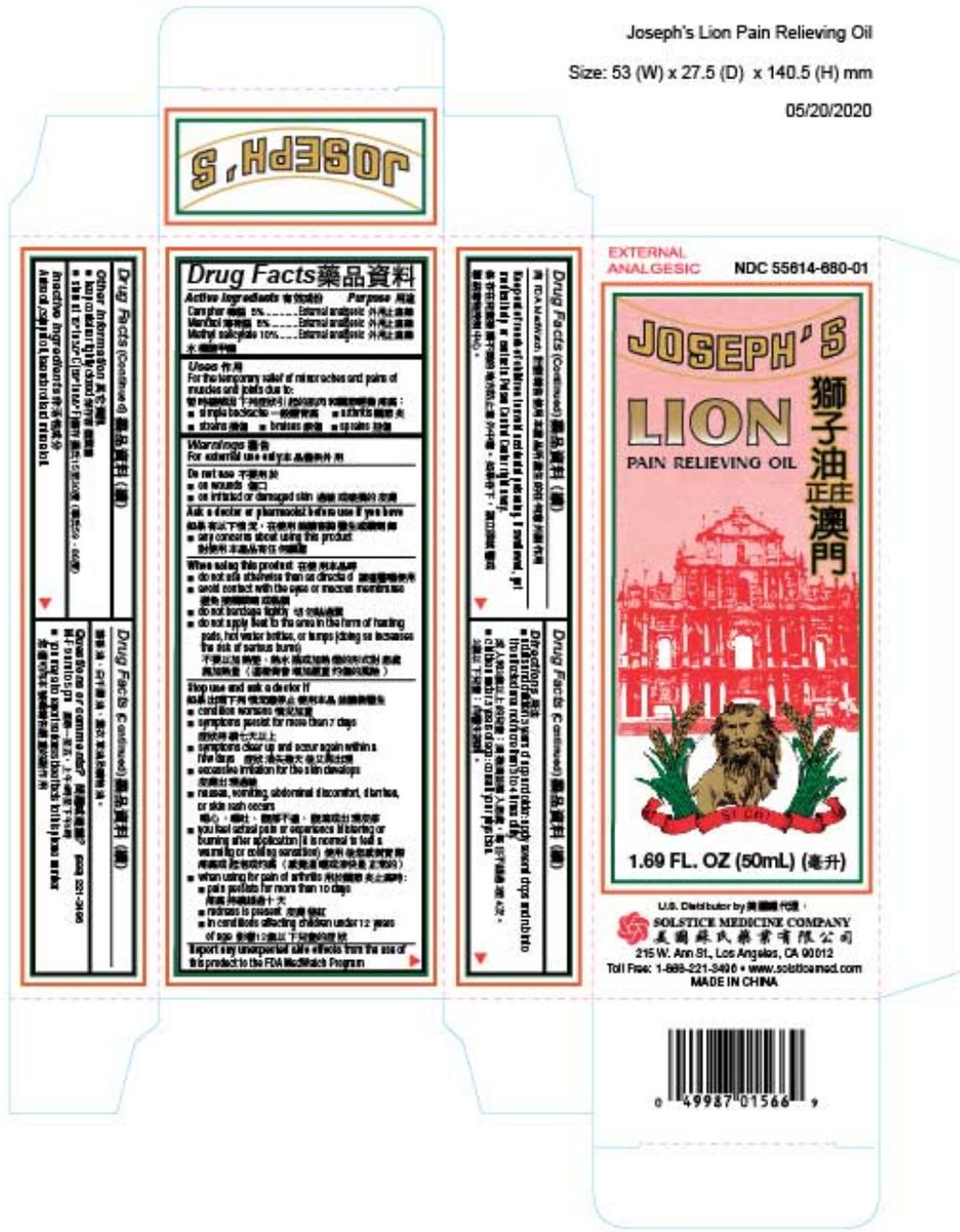
JOSEPH'S LION PAIN RELIEVING OIL

NDC-55614-680-01

EXTERNAL ANALGESIC

1.69 FL OZ (50 ML)

Joseph's Lion Pain Relieving Oil  
 Size: 53 (W) x 27.5 (D) x 140.5 (H) mm  
 05/20/2020



# JOSEPHS LION PAIN RELIEVING

camphor, menthol, methyl salicylate oil

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55614-680
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 g in 100 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	8 g in 100 mL
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANISE OIL</b> (UNII: 6Y89129C8H)	
<b>CAJUPUT OIL</b> (UNII: J3TO6BUQ37)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-680-01	1 in 1 BOX	06/04/2020	
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 Drug	M017	06/04/2020	

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

**Registrant** - MADISON ONE ACME INC (096196758)

## Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-680)