

**SOLSTICE PAIN RELIEVING- camphor, menthol, methyl salicylate patch**  
**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 3.1%

Menthol 6.0%

Methyl salicylate 10.0%

***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**

- 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 patch]

**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.** If swallowed, get medical help or contact a Poison Control Center right away.

### ***Directions***

- adults and children 3 years of age and older:
  - clean and dry affected area
  - remove the protective film from the patch
  - apply patch to affected area not more than 3 to 4 times daily
  - remove patch from the skin after at most 8-hour application
  - wet patch with warm water before removing from the skin
- children under 3 years of age: consult your physician

### ***Other information***

- keep patches tightly closed in the zip-lock pouch
- avoid excessive heat

***Inactive ingredients*** hydrogenated poly, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, petroleum, and styrene/isoprene copolymer.

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

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

Solstice Pain Relieving Patch

Large

Camphor 3.1%, Menthol 6.0%, Methyl Salicylate 10%

NDC 55614-310-06

6 Patches, Each Patch 5.67 in x 3.62 in (14.4 cm x 9.2 cm)

Solstice Pain Relieving Patch (Large) 6ct  
09/10/2019

117x20x177mm

177



20

PRESS OPEN

# Solstice

Pain Relief Patch

Drug Facts		Drug Facts (continued)
<b>Active Ingredients</b>	<b>Purpose</b>	<ul style="list-style-type: none"> <li>when using for pain of arthritis:                             <ul style="list-style-type: none"> <li>pain persists for more than 10 days</li> <li>redness is present</li> <li>in conditions affecting children under 12 years of age</li> </ul> </li> </ul>
Camphor 3.1% Menthol 6.0% Methyl salicylate 10.0%	External analgesic External analgesic External analgesic	<p>Report any unexpected side effects from the use of this product to the FDA MedWatch Program.</p> <p>Keep out of reach of children. If allowed, get medical help or contact a Poison Control Center right away.</p>
<b>Uses</b>	For the temporary relief of minor aches and pains of muscles and joints due to: <ul style="list-style-type: none"> <li>simple backache</li> <li>arthritis</li> <li>sprains</li> <li>bruises</li> <li>sprains</li> </ul>	<b>Directions</b>
<b>Warnings</b>	For external use only. Do not use: <ul style="list-style-type: none"> <li>on irritated or damaged skin</li> <li>on wounds</li> </ul> <p>Ask a doctor or pharmacist before use if you have any concerns about using this product.</p> <p><b>When using this product:</b></p> <ul style="list-style-type: none"> <li>avoid contact with the eyes or mucous membranes</li> <li>do not bandage tightly</li> <li>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)</li> <li>avoid placing on extremely hairy areas of skin to avoid irritation upon removing the patch</li> </ul> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> <li>condition worsens</li> <li>symptoms persist for more than 7 days</li> <li>symptoms clear up and occur again within a few days</li> <li>irritation of the skin develops</li> <li>nausea/vomiting, abdominal discomfort, diarrhea, or skin rash occurs</li> <li>you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation)</li> </ul>	<ul style="list-style-type: none"> <li>adults and children 12 years of age and older:                             <ul style="list-style-type: none"> <li>clean and dry affected area</li> <li>remove the protective film from the patch</li> <li>apply patch to affected area not more than 2 to 4 times daily</li> <li>remove patch from the skin after at most 8-hour application</li> <li>wash patch with warm water before removing from the skin</li> <li>children under 12 years of age: consult your physician</li> </ul> </li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>keep patches tightly closed in the zip-lock pouch</li> <li>avoid excessive heat</li> </ul>	<b>Inactive Ingredients</b>
		hydrogenated poly, pentaerythrityl tetra-di-1-butyl hydroxydiphenylmethane, petroleum, and ethylene glycol dimethyl acrylate.
<b>Questions or comments?</b>		<p>(800) 221-2420 M-F 9 am to 5 pm                      * you may also report serious side effects to this phone number</p>

Distributed by:  
**SOLSTICE MEDICINE COMPANY**  
 美国拜耳医药有限公司  
 215 W. Ann Street, Los Angeles, CA 90012  
 Toll Free: 1-888-221-2420  
 www.solsticemed.com  
 Made in China



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Solstice Pain Relieving Patch (Large) 6ct  
09/10/2019

117x20x177mm

PRESS OPEN

**Drug Facts**

Active Ingredients	Purpose
Camphor 3.1%	External analgesic
Menthol 6.0%	External analgesic
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• 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

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**Other Information**  
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• avoid excessive heat

**Inactive Ingredients**  
hydrogenated poly, pentaerythrityl tetra-di-1-butyl hydroxydiphenylmethane, petroleum, and ethylmethylacrylate copolymer

**Questions or comments?**  
(800) 221-2426 M-F 9 am to 5 pm  
• you may also report serious side effects to this phone number

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美商拜耳医药有限公司  
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## SOLSTICE PAIN RELIEVING

camphor, menthol, methyl salicylate patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:556 14-310
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.1 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
LIQUID PETROLEUM (UNII: 6ZAE7X688J)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-310-06	6 in 1 BOX	07/29/2019	
1		9 g in 1 PATCH; 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	07/29/2019	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(55614-310)

Revised: 12/2019

MADISON ONE ACME INC