

**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.*

-----

**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

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

NDC 55614-210-20

20 Patches, Each Patch 2.83 in x 1.81 in (7.2 cm x 4.6 cm)



Solstice Pain Relieving Patch (20ct)  
 Size: 81mm x 19mm x 114mm  
 09/10/2019

**PRESS  
 OPEN**

**Drug Facts**

**Active Ingredients Purpose**  
 Camphor 3.1% External analgesic  
 Menthol 6.0% External analgesic  
 Methyl salicylate 10.0% External analgesic

**Directions:** For the temporary relief of minor aches and pains of muscles and joints due to:  
 • muscle 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 change tight clothing  
 • 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 patches on extremely hairy areas of skin to avoid irritation upon removing the patch  
 Slip case and ask a doctor if:  
 • condition worsens  
 • symptoms persist for more than 7 days  
 • if patches clear up and occur again within 48 hours  
 • unexplained irritation of the skin develops, dizziness, or skin rash occurs  
 • you feel dizziness or experience blurring of vision 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  
 • becomes a constant

**Drug Facts (continued)**

• In conditions affecting children under 12 years of age:  
 Report any neurological signs or symptoms 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 at once.

**Directions:**  
 • adults and children 12 years of age and older:  
 • clean and dry affected area  
 • remove the product as far from the patch as possible  
 • apply patch to affected area not more than 2 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 12 years of age: consult your pediatrician

**Other information:**  
 • keep patches tightly closed in the zip-lock pouch  
 • avoid excessive heat

**Inactive ingredients:**  
 hydroxyethyl cellulose, polyethylene glycol, methyl salicylate, butyl alcohol, phthalocyanine, polyethylene glycol, and aluminum hydroxide copolymer.

**Questions or comments?**  
 888-221-3465 M-F 9 am to 5 pm  
 • We may also report serious side effects to the public number.

Manufactured by:  
 HELLERICH INDUSTRIES COMPANY  
 4, 66, 68, 69, 70, 71, 72, 73, 74  
 210 W. Arroyo Street, Los Angeles, CA 90012  
 Toll Free: 1-888-221-3465  
 www.hellerich.com  
 Made in China

Solstice Pain Relieving Patch  
 Camphor 3.1%, Menthol 6.0%, Methyl Salicylate 10%  
 NDC 55614-210-60  
 60 Patches in 3 Pouches, 20 Patches per Pouch  
 Each Patch 2.83 in x 1.81 in (7.2 cm x 4.6 cm)



Solstice Pain Relieving Patch (60ct)  
 Size: 81mm x 48mm x 114mm  
 09/10/2019

**Solstice Pain Relieving Patch**

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

NDC 55614-210-02

2 Patches, Each Patch 2.83 in x 1.81 in (7.2 cm x 4.6 cm)

Sample Only / Not For Re-Sale

Pouch size: 164 x 113mm



## SOLSTICE PAIN RELIEVING

camphor, menthol, methyl salicylate patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:556 14-210
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:55614-210-20	20 in 1 BOX	07/26/2019	
1		9 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:55614-210-60	60 in 1 BOX	07/26/2019	
2		9 g in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:55614-210-02	2 in 1 POUCH	07/26/2019	
3		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	07/26/2019	

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

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(55614-210)

Revised: 12/2019

MADISON ONE ACME INC