

SOLSTICE PAIN RELIEVING- camphor, menthol, methyl salicylate patch
MADISON ONE ACME INC

Drug Facts

Active ingredient

Camphor 3.1%

Menthol 6.0%

Methyl salicylate 10.0%

Purpose

External analgesic

External analgesic

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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, pentaerythryl 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)

177



Solstice Pain Relieving Patch (Large) 6ct
09/10/2019
117x20x177mm



117

20



177

20

SOLSTICE PAIN RELIEVING

camphor, menthol, methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-310
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 Drug	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: 11/2024

MADISON ONE ACME INC