

**SOLSTICE CAPSAICIN PATCH HOT- capsaicin 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

Capsaicin 0.025%

Purpose

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 12 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 12 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 Capsaicin Patch Hot

Capsaicin 0.025%

NDC 55614-410-01

1 Patches, Each Patch 5.12 in x 7.09 in (13 cm x 18 cm)



Solstice Capsaicin Patch Hot

Capsaicin 0.025%

NDC 55614-410-03

3 Patches, Each Patch 5.12 in x 7.96 in (13 cm x 18 cm)



Size: 180mm x 252mm • 09/11/2019

SOLSTICE CAPSAICIN PATCH HOT

capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1Z M) (CAPSAICIN - UNII:S07O44R1Z M)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED POLYDECENE (550 MW) (UNII: U333R16EB7)	
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:55614-410-01	1 in 1 POUCH	09/18/2019	
1		9 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:55614-410-03	3 in 1 POUCH	09/18/2019	
2		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	09/18/2019	

Labeler - MADISON ONE ACME INC (096196758)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(55614-410)

Revised: 11/2022

MADISON ONE ACME INC