

EXTRA STRENGTH HUA TUO PAIN RELIEF- camphor and menthol 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 Ingredients

Camphor 3.1%

Menthol 2.6%

Purpose

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

Allergy alert: This product contains natural rubber latex which may cause allergic reactions.

Do not use ■ on irritated or damaged skin

- on wounds
- if you are allergic to any ingredient in this product

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 2 years of age and older: remove the protective film from the patch. Apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult your physician

Other information

- keep patches tightly closed in the zip-lock pouch
- store at 15° to 30° C (59° to 86° F) in a dry place away from sunlight

Inactive ingredients

Ocimum gratissimum leaf oil, butylated hydroxytoluene, cinnamon oil, saposchnikovia divaricata root, angelica dahurica root, ginger, lanolin, natural latex rubber, petrolatum, rosin, safflower, nepeta tenuifolia flowering top, and zinc oxide on an elastic cloth and covered with a protective paper film.

Questions or comments?

(888) 221-3496 M-F 9 am to 5 pm

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

EXTRA STRENGTH HUA TUO PAIN RELIEF PATCH

NDC 55614-630-01

An effective herbal patch for the relief of aches and pains from muscles, strains, arthritis, backache, joints, bruises, sprains.

6 Patches

Each Patch 7 x 10 cm (2.75 x 4 in)

Apply for 12 Hours

華佗跌打風濕膏紙盒 - 04/09/2020
 Size: 164mm x 104mm x 13mm

華佗跌打風濕膏 六貼裝

Drug Facts 藥品資料

Active ingredients 有效成份
 Camphor 1.0g, Menthol 0.1g, Eucalyptus 0.1g, Clove 0.1g, Turpentine 0.1g, and other natural ingredients.

Warnings 警告
 For external use only. Do not use if you are allergic to any of the ingredients. Do not use if you are pregnant or breastfeeding.

Directions 使用說明
 Rub gently on the affected area. Do not use on broken skin or near the eyes.

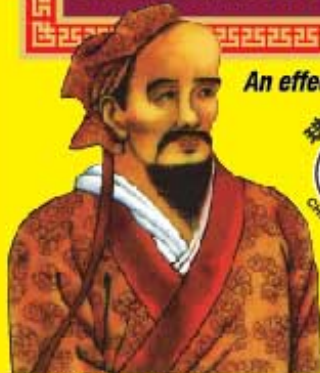
Other information 其他資訊
 Contains 6 patches. Each patch is 7 cm x 10 cm.

Drug Facts 藥品資料 (continued)

SOLSTICE
 MEDICINE COMPANY

NDC 55614-630-01

強力華佗跌打風濕膏
EXTRA STRENGTH HUA TUO PAIN RELIEF PATCH



An effective herbal patch for the relief of aches and pains from



- muscles
- strains
- arthritis
- backache
- joints
- bruises
- sprains

LOT
 EXP

6 (六貼裝) • 每貼 (7厘米x10厘米)
 PATCHES • Each Patch 7 x 10 cm (2.75 x 4 in)



HUA TUO PAIN RELIEF PATCH 6 Patches

U.S. Distributor 美國總代理
SOLSTICE MEDICINE COMPANY
 美國蘇氏藥業有限公司

215 W. Ann Street, Los Angeles, CA 90012
 Toll Free: 1-888-221-3498 www.solsticemed.com

Made in China

EXTRA STRENGTH HUA TUO PAIN RELIEF

camphor and menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-630
Route of Administration	TRANSDERMAL		

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	2.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
O CIMUM GRATISSIMUM LEAF OIL (UNII: AVG2506KDV)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
SAPOSHNIKO VIA DIVARICATA ROOT (UNII: 8H84LFK2QD)	
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
GINGER (UNII: C5529G5JPQ)	
LANOLIN (UNII: 7EV65EAW6H)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
PETROLATUM (UNII: 4T6HI2BN9U)	
ROSIN (UNII: 88S87KL877)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
NEPETA TENUIFOLIA FLOWERING TOP (UNII: 2FN3BA1MZE)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55614-630-01	1 in 1 BOX	04/01/2020	
1		6 in 1 POUCH		
1		1 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	04/01/2020	

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

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(55614-630)