# 701 DIEDA ZHENGTONG YAOGAO MEDICATED- camphor and menthol plaster 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 Ingredients**

Camphor 3.1% Menthol 5%

## 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

## Ask a doctor or pharmacist before use if you have

■ any concerns about using this product

## When using this product

- do not use otherwise than as directed
- 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)

#### 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: Cut to desired size, remove clear plastic film, and apply to affected area not more than 3 to 4 times daily.
- Children under 3 years of age: Consult your physician.

## Other information

- keep in a tightly closed container
- store at 15° to 30° C (59° to 86° F)

## **Inactive ingredients**

Angelica dahurica root, butylated hydroxytoluene, cinnamon oil, ginger, lanolin, light mineral oil, methyl salicylate, natural latex rubber, nepeta tenuifolia flowering top, ocimum gratissimum leaf oil, petrolatum, polyisobutylene, reynoutria japonica root, rheum officinale root, rosin, safflower, saposhnikovia divaricata root, scutellaria baicalensis root, zanthoxylum nitidum root and zinc oxide on an elastic cloth backing and covered with a polyethylene 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

## 701 DIEDA ZHENGTONG YAOGAO MEDICATED PLASTER

External Analgesic

Camphor and Menthol

NDC 55614-620-02

1 Plaster - 3.93 x 157 inches (10 x 400 cm)



## 701 DIEDA ZHENGTONG YAOGAO MEDICATED PLASTER

External Analgesic

Camphor and Menthol

NDC 55614-620-01

40 Plasters - Each Plaster 3.93 x 2.75 inches (10 x 7 cm)

10 Pouches, 4 Plasters Per Pouch

"701"跌打鎖痛膏(紙盒)

04/30/2020 Size: 159.5mm x 105mm x 44.5mm







## 701 DIEDA ZHENGTONG YAOGAO MEDICATED

camphor and menthol plaster

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55614-620
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	5 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
GINGER (UNII: C5529G5JPQ)	
LANOLIN (UNII: 7EV65EAW6H)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
NEPETA TENUIFOLIA FLOWERING TOP (UNII: 2FN3BA1MZE)	
O CIMUM GRATISSIMUM LEAF O IL (UNII: AVG2506KDV)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYISOBUTYLENE (800000 MW) (UNII: Y132ZOQ9H7)	
REYNOUTRIA JAPONICA ROOT (UNII: 7TRV45YZF7)	
RHEUM OFFICINALE ROOT (UNII: A47JP5ZG9M)	
<b>ROSIN</b> (UNII: 88S87KL877)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
SAPO SHNIKO VIA DIVARICATA ROOT (UNII: 8 H8 4LFK2QD)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ZANTHO XYLUM NITIDUM ROOT (UNII: L2CQZ81759)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>
1	NDC:55614-620-02	1 in 1 CAN	05/04/2020	
1		1 in 1 POUCH		
1		1 g in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:55614-620-01	10 in 1 BOX	05/04/2020	
2		4 in 1 POUCH		
2		1 g in 1 PATCH; Type 0: Not a Combination Product		

nation		
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
part348	05/04/2020	
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date

## Labeler - MADISON ONE ACME INC (096196758)

Establishment			
Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture (55614-620)

Revised: 5/2020 MADISON ONE ACME INC