

EXTRA STRENGTH HUA TUO PAIN RELIEVING- camphor and menthol plaster
Zhejiang Dingtai Pharmaceutical Co., Ltd

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 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 plaster

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 plaster. Apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult your physician

Other information

- keep plasters 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 numb

EXTRA STRENGTH HUA TUO PAIN RELIEVING PLASTERS

EXTERNAL ANALGESIC

NDC 69070-307-01

5 Plasters □ Each Plaster 7x10 cm (2.75 x 4 in)

EASY TO USE PAIN RELIEF PATCHES

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

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
OCIMUM GRATISSIMUM LEAF OIL (UNII: AVG2506KDV)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
SAPOSHNIKOVIA DIVARICATA ROOT (UNII: 8H84LFK2QD)	
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
GINGER (UNII: C5529G5JPQ)	
LANOLIN (UNII: 7EV65EAW6H)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
PETROLATUM (UNII: 4T6H12BN9U)	
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:69070-307-01	1 in 1 BOX	04/09/2019	
1		5 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	04/09/2019	

Labeler - Zhejiang Dingtai Pharmaceutical Co., Ltd (420598724)**Establishment**

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(69070-307)