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, saposhnikovia 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.

Drug Facts 藥品資料

Active Ingredients 有效成份 Camphor # 55 5.1% ... Menthal ##55 2.6% ...

Purpose 用途 External Analgesic ## 4.4 External Analgesic ## 4.4

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Warnings 警告 For external use only 宋縣井県

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Drug Facts 薬品資料 (continued) 績

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Keep out of reach of children. Fevallowed, get medical help or corect a Poison Control Center right away 我 宣称完 查提 稿不到 龄城方:如果被各套:借土即均需或解格基础检制中心

Directions 使用說明

- Apply to affected area not more than 3 to 4 times daily. 点人 3.2美ペ上 文章:京 音響上称 丁秋朝鮮 弘が名席・毎日 不明明 3.54年・ children under 2 years or age: consult your physician 2美ペア 文章:称音生解的

Other information 其他資訊

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Inactive ingredients 非活性成分 Comun quinimum led oi, but/ded hydoxyduse, o memor oi, esporbilosi discretis not, ingelias debator ret, graps, terolin, satual lates rubbes, putolate safforms, reguta terufalla flowering top, and sino oide on an electic cloth and core a protection popularitim.

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Questions or comments? 問題或意見? (888) 221-3466 M-F, Rambol pm: 4-1441 - 上台9時至746時 a you nay also report serious side fileta to fris phore number 生活可以供用性需要的概念

Manufacturer by 浙江鼎泰秦業般份有限公司

ZHEJIANG DINGTAI PHARMACEUTICAL CO., LTD.

Made In China



NDC 69070-307-01





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

> EASY TO USE PAIN RELIEF PATCHES

5 PLASTERS (五指裝) 荷貼 (7厘米x10厘米) Each Plaster 7 x 10 cm (2.75 x 4 in)

U.S. Distributor美 書畫代 雅: SOLSTICE MEDICINE COMPANY 美國蘇氏藥業者限公司

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



EXTRA STRENGTH HUA TUO PAIN RELIEVING

camphor and menthol plaster

Product Information

HUMAN OTC DRUG NDC:69070-307 Product Type Item Code (Source)

Route of Administration TRANSDERMAL

TUO PAIN RELIEVING PLASTERS

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
	CAMPHOR (SYNTHETIC)	3.1 g in 100 g			
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHO L	2.6 g in 100 g			

Inactive Ingredients		
Ingredient Name	Strength	
O CIMUM GRATISSIMUM LEAF O IL (UNII: AVG2506KDV)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
CINNAMON OIL (UNII: E5GY4I6 YCZ)		
SAPO SHNIKO VIA DIVARICATA ROOT (UNII: 8 H8 4LFK2QD)		
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)		

P	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		

$\pmb{Labeler-} \textbf{Zhe} \textit{jiang Dingtai Pharmaceutical Co., Ltd (420598724)}$

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