

EXTRA STRENGTH HUA TUO MEDICATED PLASTER - camphor, menthol, methyl salicylate plaster

GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL COMPANY

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 8.3%
Menthol 3.32%
Methyl salicylate 13.84%

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

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

Do not use

■ on irritated or damaged skin ■ on wounds ■ otherwise than as directed

When using this product

■ avoid contact with the eyes or mucous membranes
■ do not bandage tightly
■ 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
■ 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

Keep out of reach of children to avoid accidental poisoning.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ adults and children 3 years of age and older: remove the attached film from the plaster. Apply to affected area not more than 3 to 4 times daily
■ children under 3 years of age: consult your physician
■ refer to the above warnings; use otherwise than as directed may be dangerous

Other information

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

Inactive ingredients

African basil (*Ocimum gratissimum* L) herb oil, cinnamon oil, fang feng root, Formosan sweet gum (*Liquidambar formosana* Hance) Resin, fragrant angelica root extract, greater galangal root extract, ginger root extract, huo xue dan [*Glechoma longituba* (Nakai) Kuprian] aerial part, natural latex rubber, nux vomica (*Strychnos nux-vomica* L) seed, rosin, safflower flower, and schizonepeta (*Schizonepeta tenuifolia* Briq.) flowering aerial part on a cotton pad.

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

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

EXTERNAL ANALGESIC

NDC 61821-051-01

EXTRA STRENGTH HUA TUO MEDICATED PLASTER

5 Plasters per Carton

Each Plaster 7x10 cm (2.76 x 3.94 in)

華佗跌打風濕膏 五貼裝

Drug Facts 藥品資料

Active Ingredients 有效成分 **Purpose 用途**
 Camphor 樟腦 8.3% External Analgesic 外用止痛
 Menthol 薄荷醇 3.32% External Analgesic 外用止痛
 Methyl salicylate 水楊酸甲酯 13.84% External Analgesic 外用止痛

Uses 作用: For the temporary relief of minor aches and pains of muscles and joints due to: 暫時緩解由以下情況引起的肌肉和關節疼痛:
 ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains
 一般腰痛 關節炎 扭傷 瘀傷 扭傷

Warnings 告誡: For external use only 本品僅供外用。
Allergy alert 過敏警告: This product contains natural rubber latex which may cause allergic reactions. 此產品含有可能導致過敏反應的天然乳膠成份。

Do not use 不能用於:
 ■ on wounds ■ on irritated or damaged skin ■ otherwise than as directed
 創傷 受刺激或受損的皮膚 除非另有醫囑

When using this product 在使用本產品時:
 ■ avoid contact with the eyes or mucous membranes 避免接觸眼睛或黏膜
 ■ do not bandage tightly 切勿貼過緊
 ■ avoid placing on extremely hairy areas of skin to avoid irritation upon removing the plaster 避免貼在毛髮濃密處撕掉時而引起皮膚發炎

Stop use and ask a doctor if 如果出現以下症狀應停止使用或運送醫囑:
 ■ condition worsens 病情加重
 ■ symptoms persist for more than 7 days 症狀持續七天以上
 ■ symptoms clear up and occur again within a few days 症狀好轉後數天內復發
 ■ excessive irritation of the skin develops 皮膚有嚴重刺激或發炎
 ■ nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs 噁心、嘔吐、腹部不適、腹瀉或出現皮膚
 ■ when using for pain of arthritis 用於治療關節炎引起的疼痛時:
 ■ pain persists for more than 10 days 疼痛持續超過10天
 ■ redness is present 發紅
 ■ in conditions affecting children under 12 years of age 影響12歲以下兒童的症狀

Drug Facts 藥品資料 (continued) 續

Keep out of reach of children 兒童不可觸及: To avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away. 放在兒童拿不到的地方以避免意外中毒。如果被兒童意外吞食，請立即送醫或聯絡毒物控制中心。

Directions 用法:
 ■ adults and children 3 years of age and older: remove the protective film from the plaster. Apply to affected area not more than 3 to 4 times daily. 成人及3歲以上兒童：撕開貼膏的保護膜。貼在患處，每天不超過3至4次。
 ■ children under 3 years of age: consult your physician. 3歲以下兒童：遵醫囑。
 ■ refer to the above warning; use otherwise than as directed may be dangerous. 參考以上警告，不按指示使用可能導致危險。

Other Information 其它注意事項:
 ■ keep in a tightly closed container, 密封保存。
 ■ store at 15° to 30° C (59° to 86° F) 在攝氏 15° 至 30° (華氏 59° 至 86°) 溫度下儲存。

Inactive Ingredients 輔助成分:
 African basil (Ocimum gratissimum L.) herb oil, cinnamon oil, fang feng root, Formosan sweet gum (Liquidambar formosana Hance) Resin, fragrant angelica root extract, greater galangal root extract, ginger root extract, xue xue dan (Glechoma longituba (Nakai) Kuprian) aerial part, natural latex rubber, nux vomica (Strychnos nux-vomica L.) seed, rosin, safflower flower, and schizonepeta (Schizonepeta tenuifolia Briq.) flowering aerial part on a cotton pad 在棉墊上有羅勒油，肉桂油，防風，細香樹脂，白芷提取物，高麗薑提取物，生薑提取物，活血丹，天然乳膠，馬錢子，松香，紅花以及菊苣等成分。

Questions or Comments 問題或建議? (888) 221-3496
 M-F, 9 am to 5 pm 週一至週五，上午9時至下午5時
 ■ you may also report serious side-effects to this phone number. 您還可以使用這個電話號碼報告嚴重的副作用

Made in China



Lot No.
Exp. Date:

EXTERNAL ANALGESIC

NDC 61821-051-02



5 PLASTERS (五貼裝) 每貼 (7厘米x10厘米)
Each plaster 7 x 10cm (2.76 X 3.94 Inches)

◆ 新劑型 ◆ 新配方
◆ 可拉長或伸縮

Indications: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

暫時緩解下列症狀引起的肌肉和關節酸痛：
一般腰痛、關節炎、損傷、瘀傷、扭傷

U.S. Distributor: SOLSTICE MEDICINE COMPANY
 美國總代理: 美國蘇氏藥業有限公司
 215 West Ann Street,
 Los Angeles, CA 90012
 Toll Free: 1-888-221-3496
 WWW.SOLSTICEMED.COM

Manufactured by:
 廣州白云山敬修堂药业股份有限公司
 GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL CO., LTD.
 廣藥集團 Guangzhou, China

HUA TUO MEDICATED PLASTER 5 Plasters

camphor, menthol, methyl salicylate plaster

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61821-051
Route of Administration	TOPICAL, TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	8.3 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.32 g
MENTHYL SALICYLATE, (+/-) - (UNII: 43XOA705ZD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MENTHYL SALICYLATE, (+/-)-	13.84 g

Inactive Ingredients

Ingredient Name	Strength
O CIMUM GRATISSIMUM WHOLE (UNII: 7V3N80T4VS)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
SAPOSHNIKO VIA DIVARICATA ROOT (UNII: 8H84LFK2QD)	
LIQUIDAMBAR FORMOSANA RESIN (UNII: 597LBL467J)	
GREATER GALANGAL (UNII: 7Y64R856MB)	
GINGER (UNII: C5529G5JPQ)	
GLECHOMA LONGITUBA TOP (UNII: D352074L9S)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919)	
ROSIN (UNII: 88S87KL877)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
SCHIZONEPETA TENUIFOLIA FLOWERING TOP (UNII: 2FN3BA1MZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61821-051-01	5 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/17/2013	

Labeler - GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL COMPANY (654032218)

Registrant - GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL COMPANY (654032218)

Establishment

Name	Address	ID/FEI	Business Operations
GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL COMPANY		654032218	manufacture(61821-051)

Revised: 6/2013

GUANGZHOU BAIYUNSHAN JINGXIUTANG PHARMACEUTICAL COMPANY