DIEDA FENGSHI GAO MEDICATED- 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 61821-052-01

DIEDA FENGSHI GAO MEDICATED PLASTER

5 Plasters per Carton Each Plaster 7x10 cm (2.76 x 3.94 in)





廣藥集團 Guangzhou, China

camphor, menthol, methyl salicylate plaster

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61821-052
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: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	3.32 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	13.84 g	

Inactive Ingredients		
Ingredient Name	Strength	
O CIMUM GRATISSIMUM WHO LE (UNII: 7V3N80T4VS)		
CINNAMON OIL (UNII: E5GY4I6 YCZ)		
SAPO SHNIKO VIA DIVARICATA ROOT (UNII: 8 H8 4LFK2QD)		
LIQUIDAMBAR FORMOSANA RESIN (UNII: 597LBL467J)		
GREATER GALANGAL (UNII: 7Y64R856MB)		
GINGER (UNII: C5529G5JPQ)		
GLECHOMA LONGITUBA TOP (UNII: D352074L9S)		
NATURAL LATEX RUBBER (UNII: 2LQ0 UUW8 IN)		
STRYCHNOS NUX-VOMICA SEED (UNII: 269 XH139 19)		
ROSIN (UNII: 88S87KL877)		
SAFFLOWER (UNII: 4VBL71TY4Y)		
NEPETA TENUIFOLIA FLOWERING TOP (UNII: 2FN3BA1MZE)		

Packaging				
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61821-052-01	5 in 1 BOX; Type 0: Not a Combination Product	06/17/2013	

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

Labeler- GUANGZHOUBAIYUNSHAN JINGXIUTANG PHARMACEUTICAL COMPANY (654032218)

Registrant - GUANGZHOU BAIYUNSHAN JINGXIUT ANG PHARMACEUT ICAL COMPANY (654032218)

Establishment			
Name	Address	ID/FEI	Business Operations

654032218 manufacture(61821-052)

Revised: 11/2019

GUANGZHOU BAIYUNSHAN JINGXIUT ANG PHARMACEUTICAL COMPANY