

GUTONG TIEGAO PAIN RELIEVING- camphor and menthol patch
GUILIN CHINA RESOURCES TIANHE 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 ingredients

Camphor 3.1%

Menthol 1.25%

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

Do not use

on wounds

on large parts of the body for extended periods of time

on irritated or damaged skin

if properties of this product change

Ask a doctor or pharmacist before use if you are

using other medications

if pregnant or nursing

When using this product

avoid contact with the eyes or mucous membranes

do not bandage tightly

supervise use by children

use caution if prone to allergies

check carefully for hypersensitivity (skin reactions)

avoid placing on extremely hairy areas of skin to avoid irritation upon removing the patch

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

Directions

Clean the affected area. Remove the paper film from the patch, and place the patch on the affected area, so that the direction of stretch is consistent with joint action.

adults and children 8 years of age and older: apply to affected area not more than 3 to 4 times daily. Do not use this product for longer than 8 hours in one day.

children under 8 years of age: do not use, consult your physician

Other information

keep tightly sealed

store at 8 to 30 C (46 to 86 F), away from sunlight

Inactive ingredients

aluminum hydroxide, capsicum, cinnamon oil, dong-quai root, ercibe (*Erycibe obtusifolia* Benth.) stem, fragrant angelica root, frankincense oleo-gum-resin, ginger rhizome, glycerin, kadsura pepper [*Piper kadsura* (Choisy) Ohwi] stem, kaolin, polyacrylic acid, san-qi ginseng root, stephania (*Stephania sinica* Diels.) root, titanium dioxide, turmeric rhizome, and water on a fabric backing covered with 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 number

Gutong Tiegao Hydrogel Pain Relieving Patch

NDC 68007-301-01

6 Patches

Each Patch 2.75 in x 4 in (7 cm x 10 cm)

2 Patches Per Pouch



Drug Facts

Active Ingredients
Camphor 3.1% External analgesic
Menthol 1.25% External analgesic

Purpose
External analgesic

Uses: For the temporary relief of minor aches and pains of muscle and joints due to:
● simple backache ● arthritis ● strains ● bruises ● sprains

Warnings: For external use only

Do not use:
● on wounds
● on large parts of the body for extended periods of time
● on irritated or damaged skin
● if properties of this product change

Ask a doctor or pharmacist before use if you are:
● using other medications
● if pregnant or nursing

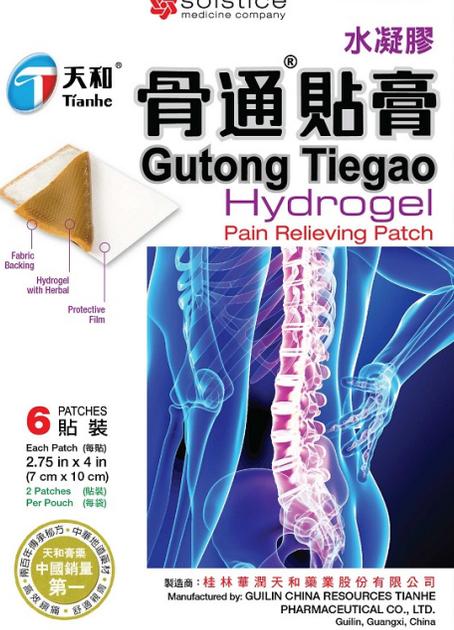
When using this product:
● avoid contact with the eyes or mucous membranes
● do not bandage tightly
● supervise use by children
● use caution if prone to allergic reactions
● check carefully for hypersensitivity (skin reactions)
● avoid placing on extremely hairy areas of skin to avoid irritation upon removing the patch

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

Exp. Date
有效期:
Lot No.
生產批號:

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

49987 01395 5
Product of China 中國產品



solstice medicine company NDC 68007-301-01

水凝膠 骨通貼膏 Hydrogel Pain Relieving Patch

天和 Tianhe 骨通貼膏 Gutong Tiegao Hydrogel Pain Relieving Patch

Fabric Backing
Hydrogel with Herbal
Protective Film

6 貼裝
Each Patch (每貼)
2.75 in x 4 in
(7 cm x 10 cm)
2 Patches (貼裝)
Per Pouch (每袋)

製造商: 桂林華潤天和藥業股份有限公司
Manufactured by: GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO., LTD.
Guilin, Guangxi, China

GUTONG TIEGAO PAIN RELIEVING

camphor and menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68007-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	248 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDRO XIDE (UNII: SQBO T2IUN0)	
CAPSICUM (UNII: 00 UK7646FG)	
CINNAMON OIL (UNII: E5GY4I6 YCZ)	
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	

ERYCIBE OBTUSIFOLIA STEM (UNII: V1G1S38CQI)
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)
FRANKINCENSE (UNII: R9XLF1R1WM)
ZINGIBER OFFICINALE WHOLE (UNII: IN6Q3S3414)
GLYCERIN (UNII: PDC6A3C0OX)
PIPER KADSURA STEM (UNII: 80IOP41EL7)
KAOLIN (UNII: 24H4NWX5CO)
POLYACRYLIC ACID (800000 MW) (UNII: D016NSZ87U)
PANAX NOTOGINSENG ROOT (UNII: GQX1C1175U)
HUPERZIA SERRATA (UNII: TLA53E5A4T)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TURMERIC (UNII: 856YO1Z64F)
WATER (UNII: 059QF0K00R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68007-301-01	3 in 1 BOX	04/13/2016	
1		2 in 1 POUCH; 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	04/13/2016	

Labeler - GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD (528565427)

Establishment			
Name	Address	ID/FEI	Business Operations
GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD		528565427	relabel(68007-301)

Establishment			
Name	Address	ID/FEI	Business Operations
FOSHAN AQUA GEL BIOTECH CO LTD		529128763	manufacture(68007-301)

Revised: 7/2018

GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD