

TIANHE GUTONG TIEGAO (IN POLYISOBUTYLENE CARRIER) - external analgesic patch patch

GUILIN 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 4%

Capsicum providing capsaicin 0.25%

Menthol 3.05%

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

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 changes

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly
- supervise use by children
- use caution if pregnant or if prone to allergies
- check carefully for hypersensitivity (skin reactions)
- if skin becomes red and or itchy, immediately remove patch

Ask a doctor or pharmacist before use if you are

- using other medications

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 2 years of age and older: apply to affected area no more than 3 to 4 times daily. Do not allow a single patch to remain in use for more than 12 hours.
- children under 2 years of age: do not use, consult your physician.

Other information

- keep tightly sealed
- store at room temperature, 15° to 30° C (59° to 86° F), away from sunlight

Inactive ingredients cinnamon oil, dong-quai root, ercibe (*Erycibe obtusifolia* Benth.) stem, fragrant angelica root, frankincense oleo-gum-resin, futokadsura [*Kadsura heteroclita* (Roxb.) Craib] stem, ginger rhizome, paraffin, san-qi ginseng root, stephania (*Stephania sinica* Diels.) root, and turmeric rhizome, in a polyisobutylene carrier covered with protective paper.

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

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

TIANHE GUTONG TIEGAO PAIN RELIEVING PATCH NDC 68007-202-01 4 PATCHES EACH
PATCH 2.75 IN X 4 IN (7 CM X 10 CM)

天和
Tianhe
中國馳名商標
The Famous Chinese Brand

骨通貼膏
Tianhe Gutong Tiegao
Pain Relieving Patch
(聚異丁烯型)
(in Polyisobutylene carrier)

Drug Facts
Active ingredients Purpose
Camphor 4% External analgesic
Capsaicin providing 0.25% External analgesic
Menthol 3.05% 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 changes

When using this product
■ avoid contact with the eyes or mucous membranes
■ do not bandage tightly
■ supervise use by children
■ use caution if pregnant or if prone to allergies
■ check carefully for hypersensitivity (skin reactions)
■ if skin becomes red and itchy, immediately remove patch

Ask a doctor or pharmacist before use if you are
■ using other medications

Stop use and ask a doctor if
■ condition worsens
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■ 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

Drug Facts (continued)
■ 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
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Product of China 中國產品

polyisobutylene

NDC 68007-202-01

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Tianhe
中國馳名商標
The Famous Chinese Brand

骨通貼膏
Tianhe Gutong Tiegao
Pain Relieving Patch
(聚異丁烯型)
(in Polyisobutylene carrier)

PIB
Polyisobutylene

4 貼裝
PATCHES
Each Patch (每貼)
2.75 in x 4 in
(7 cm x 10 cm)

製造商: **桂林天和藥業股份有限公司**
Manufactured by: **GUILIN TIANHE PHARMACEUTICAL CO., LTD**
Guilin, Guangxi, China

Tianhe Gutong Tiegao (Polyisobutylene) 天和骨通貼膏 (聚異丁烯型)

Tianhe Gutong Tiegao (Polyisobutylene) 天和骨通貼膏 (聚異丁烯型)

2010/04

TIANHE GUTONG TIEGAO (IN POLYISOBUTYLENE CARRIER)

external analgesic patch patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68007-202
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	4 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.05 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68007-202-01	4 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/24/2010	

Labeler - GUILIN TIANHE PHARMACEUTICAL CO LTD (528565427)**Establishment**

Name	Address	ID/FEI	Business Operations
GUILIN TIANHE PHARMACEUTICAL CO LTD		528565427	manufacture

Revised: 5/2010

GUILIN TIANHE PHARMACEUTICAL CO LTD