TIANHE GUTONG TIEGAO - 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 3.5%

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 prone to allergies
- check carefully for hypersensitivity (skin reactions)
- avoid placing on extremely hairy areas of skin to avoid irritation upon removing the patch

Ask a doctor or pharmacist before use if you are

- using other medications
- if pregnant or nursing

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:
- o pain persists for more than 10 days
 - redness is present
 - o 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 dong-quai root, erycibe (Erycibe obtusifolia Benth.) stem, fragrant angelica root, frankincense oleo-gum-resin, ginger rhizome, futokadsura [Kadsura heteroclita (Roxb.) Craib] stem, lanolin, paraffin, petrolatum, rosin, san-qi ginseng root, stephania (Stephania sinica Diels.) root, and zinc oxide, on a rubberized fabric backing 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 68007-201-01 10 PATCHES EACH PATCH 2.75 IN X 4 IN (7 CM X 10 CM)



Tianhe Gutong Tiegao



Pain Relieving Patch

Drug Facts

Active ingredients	Purpose
Camphor 3.5%	External analgesic
Capsicum providing capsaicin 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 Hamal use only

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

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 he yes 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

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

- Stop use and ask a doctor if
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 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:



SOLSTICE MEDICINE COMPANY 美国蘇氏幕常有限公司 215 West Ann Street, Los Angeles, CA 90012 Toll Free: 1-888-221-3496

Drug Facts (continued)

- when using for pain of arthritis:
 pain persists for more than 10 days
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 12 years of age

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Tianhe Gutong Tiegao pain relieving patch Tíanhe

Each Patch (每貼

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

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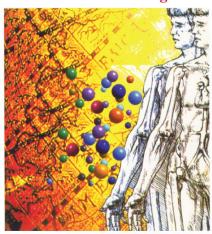
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GUILIN TIANHE PHARMACEUTICAL CO., LTD

Guilin, Guangxi, China

TIANHE GUTONG TIEGAO

external analgesic patch patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68007-201
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Route of Administration TRANSDERMAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII:N20 HL7Q941)	CAMPHOR (NATURAL)	3.5 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.05 g

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68007-201-01	10 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