

**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.*

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**Drug Facts**

***Active ingredients***

Camphor 4%

Menthol 1.8%

***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 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** to avoid accidental poisoning. 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***

capsicum, cinnamon oil, dong-quai root, ercibe (*Erycibe obtusifolia* Benth.) stem, fragrant angelica root, frankincense oleo-gum- resin, ginger rhizome, kadsura pepper [*Piper kadsura* (Choisy) Ohwi] stem, lanolin, petrolatum, rosin, san-qi ginseng root, stephania (*Stephania sinica* Diels.) root, turmeric rhizome, and zinc oxide, on a rubberized 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 Pain Relieving Patch

NDC 68007-300-01

10 Patches

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

5 Patches Per Pouch



## GUTONG TIEGAO PAIN RELIEVING

camphor and menthol patch

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68007-300 |
| Route of Administration | TOPICAL        |                    |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength   | Strength |
|--|---------------------|----------|
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 43.9 mg  |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)                         | MENTHOL             | 18.8 mg  |

### Inactive Ingredients

| Ingredient Name                 | Strength |
|---------------------------------|----------|
| CAPSICUM (UNII: 00UK7646FG)     |          |
| CINNAMON OIL (UNII: E5GY416YCZ) |          |

|  |  |
|--|--|
| ANGELICA SINENSIS ROOT (UNII: B66F4574UG)    |  |
| ERYCIBE OBTUSIFOLIA STEM (UNII: V1G1S38CQI)  |  |
| ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)    |  |
| FRANKINCENSE (UNII: R9XLF1R1WM)              |  |
| ZINGIBER OFFICINALE WHOLE (UNII: IN6Q3S3414) |  |
| PIPER KADSURA STEM (UNII: 80IOP41EL7)        |  |
| LANOLIN (UNII: 7EV65EAW6H)                   |  |
| PETROLATUM (UNII: 4T6H12BN9U)                |  |
| ROSIN (UNII: 88S87KL877)                     |  |
| PANAX NOTOGINSENG ROOT (UNII: GQX1C1175U)    |  |
| HUPERZIA SERRATA (UNII: TLA53E5A4T)          |  |
| TURMERIC (UNII: 856YO1Z64F)                  |  |
| ZINC OXIDE (UNII: SOI2LOH54Z)                |  |
| NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)      |  |

### Packaging

| # | Item Code        | Package Description                             | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68007-300-01 | 2 in 1 BOX                                      | 04/14/2016           |                    |
| 1 |                  | 5 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                                  | 04/14/2016           |                    |

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

### Establishment

| Name  | Address | ID/FEI    | Business Operations    |
|---|---------|-----------|------------------------|
| GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD |         | 528565427 | manufacture(68007-300) |

Revised: 5/2018

GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD