

TIANHE ZHUANGGU GAO - pain relieving plaster plaster
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 3.22%

Menthol 1.39%

Methyl salicylate 15.01%

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 irritated or damaged skin
- on wounds
- with a heating pad
- if pregnant or nursing
- otherwise than as directed

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly

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 plaster.

- adults and children 12 years of age and older: apply one plaster to affected area not more than 3 to 4 times daily
- children under 12 years of age: do not use, consult your physician
- refer to the above warnings; use otherwise than as directed may be dangerous

Other information

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

Inactive ingredients dong quai root, ginger rhizome, lanolin, paraffin, petrolatum, rosin, 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 ZHANGGU GAO PAIN RELIEVING PLASTER NDC 68007-203-01 10 PLASTERS EACH PLASTER 2.27 IN X 4 IN (7 CM X 10 CM)

天和壯骨膏 Tianhe Zhuanggu Gao
2010/04



TIANHE ZHUANGGU GAO
pain relieving plaster plaster

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68007-203
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	3.22 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.39 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	15.01 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68007-203-01	10 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/25/2010	

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