TIANHE ZHUIFENG GAO - camphor, capsaicin and menthol 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 4.75%
Capsicum providing capsaicin 0.25%
Menthol 1.4%

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 irritated or damaged skin

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. 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 and place the plaster on the affected area.

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
- 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)

Inactive ingredients cinnamon oil, dong-quai root, dragon's blood resin, frankincense oleo-gum-resin, lanolin, paraffin, petrolatum, pubescent angelica root, safflower flowers, rosin, and zinc oxide, on a rubber 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 ZHUIFENG GAO PAIN RELIEVING PLASTER NDC 68007-204-01 10 PLASTERS EACH PLASTER 2.75 IN X 4 IN (7 CM X 10 CM)



TIANHE ZHUIFENG GAO camphor, capsaicin and menthol plaster Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68007-204 Route of Administration TRANSDERMAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	4.75 g			
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 g			
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.4 g			

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:68007-204-01	10 in 1 BOX					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	05/27/2010				

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