

ZHUANGGU GAO PAIN RELIEVING- menthol plaster
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.

Drug Facts

Active Ingredients

Menthol 3.5%

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 irritated or damaged skin
- if you are allergic to any ingredient in this product

Ask a doctor or pharmacist before use if you have

- any concerns about using this product

When using this product

- avoid contact with the eyes or mucous membranes
- do not bandage tightly
- do not apply heat to the area in form of heating pads, hot water bottles, or lamps (doing so increases the risk of serious burns)
- avoid placing on extremely hairy areas of skin to avoid irritation upon removing the plaster

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
- you feel actual pain or experience blistering or burning after application (it is normal to feel a warming or cooling sensation)
- 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

- adults and children 2 years of age and older: remove the protective film from the plaster. Apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult your physician.

Other information

- keep plasters tightly closed in the zip-lock pouch
- store at 15 to 30 C (59 to 86 F) in a dry place away from sunlight

Inactive ingredients angelica sinensis root, cang-zhu atractylodes rhizome, fragrant angelica root, ginger rhizome, kaempferia galanga rhizome, lanolin, mineral oil, petrolatum, rosin, rubber, star anise fruit, styrene-isoprene, and zinc oxide on a 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

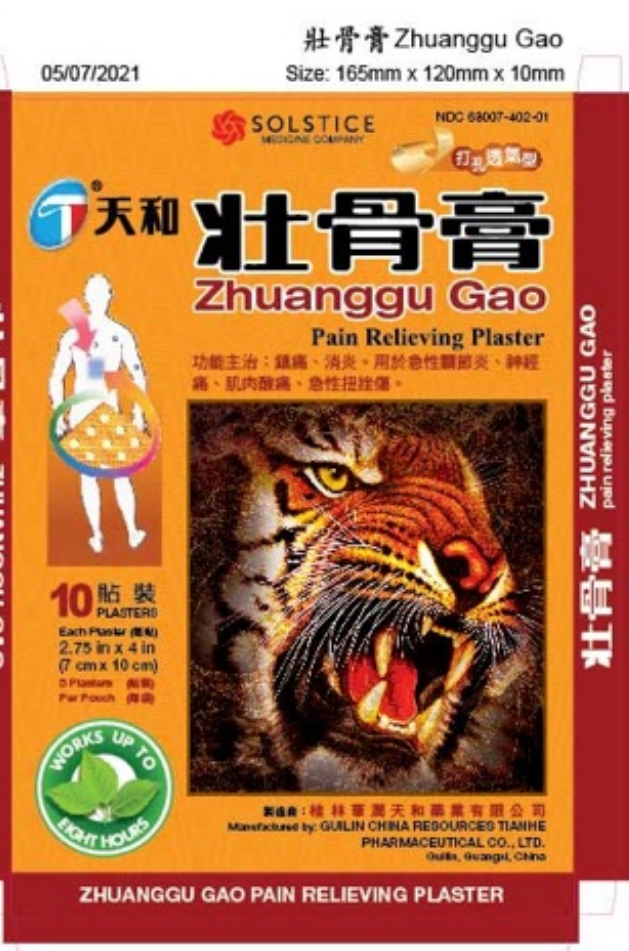
Zhuanggu Gao Pain Relieving Plaster

NDC 68007-402-01

10 Patches

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

5 Patches per Pouch



ZHUANGGU GAO PAIN RELIEVING

menthol plaster

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68007-402
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	35 mg

Inactive Ingredients

Ingredient Name	Strength
ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
ATRACTYLODES LANCEA ROOT (UNII: CAZ 6282J2O)	
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
GINGER (UNII: C5529G5JPQ)	
KAEMPFERIA GALANGA ROOT (UNII: 7B7U9D12AI)	
LANOLIN (UNII: 7EV65EAW6H)	

MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
ROSIN (UNII: 88S87KL877)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
STAR ANISE FRUIT (UNII: CK15HA8438)	
STYRENE (UNII: 44LJ2U959V)	
ISOPRENE (UNII: 0A62964IBU)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68007-402-01	2 in 1 BOX	05/10/2021	
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	05/10/2021	

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(68007-402)

Revised: 5/2021

GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD