GUTONG TIEGAO 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 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 have

- 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 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 tightly sealed
- store at 8 to 30 C (46 to 86 F), away from sunlight

Inactive ingredients angelica sinensis root, cinnamon oil, erycibe (Erycibe obtusifolia Benth.) stem, fragrant angelica root, frankincense oleo-gum-resin, ginger rhizome, kadsura pepper [Piper kadsura (Choisy) Ohwi] stem, lanolin, paprika, petrolatum, rosin, rubber, san-qi ginseng root, stephania (Stephania sinica Diels.) root, styrene-isoprene, turmeric rhizome, 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

Gutong Tiegao Pain Relieving Plaster

NDC 68007-400-01

10 Patches
Each Patch 2.75 in x 4 in (7 cm x 10 cm)
5 Patches per Pouch



GUTONG TIEGAO PAIN RELIEVING

menthol plaster

Product Information

GINGER (UNII: C5529G5JPQ)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68007-400

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)	
CINNAMON OIL (UNII: E5GY4I6YCZ)	
ERYCIBE OBTUSIFOLIA STEM (UNII: V1G1S38CQI)	
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)	
FRANKINCENSE (UNII: R9XLF1R1WM)	

PIPER KADSURA STEM (UNII: 80IOP41EL7)	
LANOLIN (UNII: 7EV65EAW6H)	
PAPRIKA (UNII: X72Z47861V)	
PETROLATUM (UNII: 4T6H12BN9U)	
ROSIN (UNII: 88S87KL877)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
PANAX NOTOGINSENG ROOT (UNII: GQX1C1175U)	
STEPHANIA SINICA WHOLE (UNII: 529T7EWP3I)	
STYRENE (UNII: 44LJ2U959V)	
ISOPRENE (UNII: 0A62964IBU)	
TURMERIC (UNII: 856YO1Z64F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68007-400- 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(68007-400)	

Revised: 5/2021 GUILIN CHINA RESOURCES TIANHE PHARMACEUTICAL CO LTD