

TONG LUO QU TONG GAO - camphor and menthol poultice
HENAN LINGRUI 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 LISTING

Active ingredients

Camphor 5%

Menthol 3.4%

Purposes

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
- if the appearance of this product has changed
- in excess of 12 hours
- if you have known hypersensitivities to this product
- otherwise than as directed

Ask a doctor or pharmacist before use if you are

- pregnant
- taking other medications

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 allergic reactions

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
- 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

- adults and children 12 years of age and older: Apply one or two plasters to affected area once a day. Remove after 12 hours.
- children 2 to 12 years of age and adults with compromised health: Use only under the guidance of a doctor
- children under 2 years of age: Do not use, consult a doctor

Refer to the above warnings; use otherwise than as directed may be dangerous.

Other information

- keep container tightly closed
- store below 20° C (68E F) in a dry area

Inactive ingredients Chinese rhubarb rhizome and root, cinnamon bark, clove, dimethyl sulfoxide, dong-quai root, ginger rhizome, greater galangal rhizome, green peppercorns, lanolin, long pepper (*Piper longum* L.) fruit, paraffin, petrolatum, rosin, safflower flowers, Sichuan lovage rhizome, Sichuan pepper [*Zanthoxylum piperitum* (L.) DC.] peel, and zinc oxide, on a rubberized fabric support with a paper backing.

Questions or comments? (888) 221-3496 M-F 9 am to 5 pm

TONG LUO QU TONG GAO PAIN RELIEVING POULTICE NDC 44217-100-01 4 PLASTERS
EACH PLASTER 2.75 IN X 3.94 IN (7 CM X 10 CM)
2009年9月 通絡祛痛膏 (A稿)

| | |
|---|--|
| <p>Drug Facts 藥品資料</p> <p>Active ingredients 有效成份 Purposes 用途 Camphor 5% 樟腦 External analgesic 外部止痛 Menthol 3.4% 薄荷腦 External analgesic 外部止痛</p> <p>Uses 作用 For the temporary relief of minor aches and pains of muscles and joints due to: 暫時緩解由以下情況引起的肌肉和關節疼痛: ■ simple backache 一般腰酸背痛 ■ arthritis 關節炎 ■ strains 扭傷 ■ bruises 瘀傷 ■ sprains 扭傷</p> <p>Warnings 警告 For external use only 只供外部使用</p> <p>Allergy alert: This product contains natural rubber latex which may cause allergic reactions 過敏警告: 本產品含有天然膠乳, 可能導致過敏反應</p> <p>Do not use 不適用於 ■ on wounds 傷口 ■ on irritated or damaged skin 受刺激或受傷的皮膚 ■ if the appearance of this product has changed 如果產品的外觀有改變 ■ in excess of 12 hours 超過12小時 ■ if you have known hypersensitivities to this product 如果對本產品有已知的過敏反應 ■ otherwise than as directed 除指示以外的情況</p> <p>Ask a doctor or pharmacist before use if you are 在使用前諮詢醫生或藥劑師, 如果您 ■ pregnant 已懷孕 ■ taking other medications 正在服用其他藥物</p> <p>When using this product 在使用本產品時 ■ avoid contact with the eyes or mucous membranes 避免接觸眼睛或黏膜 ■ do not bandage tightly 避免包紮過緊 ■ supervise use by children 指導兒童使用 ■ use caution if prone to allergic reactions 過敏反應體質慎用</p> <p>Stop use and ask a doctor if 症狀持續超過7天 ■ condition worsens 病情加重 ■ symptoms persist for more than 7 days 症狀持續超過7天 ■ symptoms clear up and occur again within a few days 症狀消失但幾天後復發 ■ excessive irritation of the skin develops 皮膚出現過度刺激</p> | <p>Drug Facts (cont.) 藥品資料 (續)</p> <p>■ when using for pain of arthritis: 用於治療關節炎引起的疼痛時: ■ pain persists for more than 10 days: 疼痛持續超過10天 ■ redness is present 發紅 ■ in conditions affecting children under 12 years of age 影響12歲以下兒童的症狀</p> <p>Keep out of reach of children. 放置在兒童夠不到的地方。If swallowed, get medical help or contact a Poison Control Center right away. 如果被兒童意外吞食, 請立即送醫或聯絡毒品控制中心。</p> <p>Directions 使用說明 adults and children 12 years of age and older 成人及12歲以上兒童: Apply one or two plasters to affected area once a day. Remove after 12 hours. 每天貼一至兩貼於患處。12小時後取下。 children 2 to 12 years of age and adults with compromised health 2至12歲兒童及有健康問題的成人: Use only under the guidance of a doctor 在醫生指導下使用。 children under 2 years of age 2歲以下兒童: Do not use, consult a doctor 不可使用, 或向醫生諮詢</p> <p>Refer to above warnings; use otherwise than as directed may be dangerous. 參考以上警告, 不按說明使用會導致危險。</p> <p>Other information 其它資訊 ■ keep container tightly closed 將容器密封 ■ store below 20°C (68°F) in a dry area 在乾燥處於攝氏20度(華氏68度)下儲存</p> <p>Inactive ingredients 輔助成份 Chinese rhubarb rhizome and root, cinnamon bark, clove, dimethyl sulfoxide, dong-quai root, ginger rhizome, greater galangal rhizome, green peppercorns, lanolin, long pepper (<i>Piper longum</i> L.) fruit, paraffin, petrolatum, rosin, safflower flowers, sichuan lovage rhizome, sichuan pepper [<i>Zanthoxylum piperitum</i> (L.) DC.] peel, and zinc oxide, on a rubberized fabric support with a paper backing. 大黃、肉桂、丁香、當歸、干姜、山奈、花椒、華荳蔻、松香、紅花、川芎、胡椒、綠萼、氧化鋅、羊毛脂、石蠟、二甲苯亞砘。將這些成分置在膠布上, 用紙板覆蓋。</p> <p>Questions or comments? 問題或意見? (888)221-3496 M-F 9 am to 5 pm 週一至週五 上午9時至下午5時</p> |
|---|--|

U.S. Distributor: 美國總代理: SOLSTICE MEDICINE COMPANY 美國蘇氏藥業有限公司
215 West Ann Street, Los Angeles, CA 90012
Toll Free: 1-888-221-3496 WWW.SOLSTICEMED.COM

Exp. Date: Lot No. Made in China 中國製造

TONG LUO QU TONG GAO

camphor and menthol poultice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42217-100 |
| Route of Administration | TRANSDERMAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 5 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 3.4 g |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:42217-100-01 | 4 in 1 BOX | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part348 | 06/02/2010 | |

Labeler - HENAN LINGRUI PHARMACEUTICAL CO LTD (530021062)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|----------------|---------------|----------------------------|
| HENAN LINGRUI PHARMACEUTICAL CO LTD | | 530021062 | manufacture |

Revised: 6/2010

HENAN LINGRUI PHARMACEUTICAL CO LTD