

ZIHUA EMBROCATION COOLING PAIN RELIEF- camphor menthol methyl salicylate oil
Uncle Bill Trading USA Inc.

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 11%

Menthol 15%

Methyl salicylate 15%

Purpose

external analgesic

external analgesic

external analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

- **For external use only**
- avoid getting into the eyes or on mucous membranes
- discontinue use if excessive irritation of the skin develops

When using this product

- do not apply to wound or damaged skin.
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- Pain persists for more than 10 days conditions
- redness is present
- conditions affect 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 12 years of age and older apply to affected area not more than 3 to 4 time daily
- Apply liberally and gently rub into affected area
- Children under 12 years of age, consult a doctor before using
- Do not use otherwise than as directed

Inactive ingredients

Eucalyptus oil, FDC Blue No. 1 Al Lake, FDC Red No. 40 Al Lake, lavender oil, mineral oil

Package Label

紫花油
ZIHUA EMBROCATION

美國總代理
Distributed by :
Uncle Bill (USA)
Trading Inc.
85B Allen St.,
NY, NY10002

香港製造
Product of
Hong Kong

Drug Facts (continued) 藥品資料 (續)
Inactive ingredients 輔助成分
Eucalyptus oil, FD&C Blue No. 1 AI Lake,
FD&C Red No. 40 AI Lake, lavender oil, mineral oil,
松油, 藍1色淀, 紅40色淀, 薰衣草油, 液狀石蠟



ZIHUA
EMBROCATION

**外用止痛
舒緩痛楚**

Topical
Analgesic Oil

Cooling
Pain Relief

紫花油



26毫升
0.9液盎司
26 mL
0.9 FL. OZ



Manufacturer :
HONG KONG ZIHUA
PHARMACEUTICAL
LTD.

Flat / Rm E & F,
2/F, Block F, East Sun
Industrial Centre,
16 Shing Yip St.,
Kwun Tong,
Kowloon.

香港紫花油大藥廠
有限公司
九龍觀塘成業街
16 號怡生工業中心
2樓E及F座

HK Registration
No. of pCm /
香港中成藥
註冊編號
HKC-16478

Drug Facts 藥品資料

Active ingredients 主要成分 **Purpose 作用**
Camphor 樟腦11% external analgesic止痛
Menthol 薄荷腦15% external analgesic止痛
Methyl salicylate 水楊酸甲酯15% external analgesic止痛

Uses 用途 For the temporary relief of minor aches
and pains of muscles and joints associated with:
■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains
適用於 ■ 肌肉及關節疼痛 ■ 腰酸背痛 ■ 跌打扭傷 ■ 瘀傷

Warnings 注意 ■ For external use only
■ avoid getting into the eyes or on mucous membranes
■ discontinue use if excessive irritation of the skin develops
■ 只供外用 ■ 避免觸及眼睛及黏膜
■ 如用後出現敏感反應，立即停止使用

When using this product 使用產品時
■ do not apply to wounds or damaged skin
■ do not bandage tightly
■ 勿塗用於破損皮膚或傷口 ■ 勿用繃帶包扎過緊

Stop use and ask a doctor if 如有下列情況，請停止使用並諮詢醫生
■ condition worsens, or it symptoms persist for more than 7 days
or clear up and occur again within a few days
■ Pain persists for more than 10 days ■ redness is present
■ conditions affect children under 12 years of age
■ 情況加重，或症狀持續超過7天，或幾天內症狀消除後再發生
■ 疼痛持續超過10天 ■ 紅腫持續 ■ 12歲以下兒童使用後不適

Keep out of reach of children to avoid accidental poisoning.
If swallowed, get medical help or contact a poison control center
right away.
放在兒童不能觸及的地方，避免意外中毒。如誤服，請立即與醫
生或毒物控制中心聯系。

Directions 使用說明
■ Adults and children 12 years of age and older apply to affected
area not more than 3 to 4 times daily
■ Apply liberally and gently rub into affected area
■ Children under 12 years of age, consult a doctor before using
■ Do not use otherwise than as directed
■ 成人及12歲以上人士，將藥油塗抹患處，每日3-4次
■ 輕輕按摩患處 ■ 12歲以下兒童，使用前請諮詢醫生意見
■ 勿用於指示以外的用途

LOT NO.:
生產批號:
Exp. Date:
失效日期:
AA / MM / DD
年 / 月 / 日

ZIHUA EMBROCATION COOLING PAIN RELIEF

camphor menthol methyl salicylate oil

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49952-004 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---------------------|-------------------|
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET) | CAMPHOR (SYNTHETIC) | 11 g in 100 mL |

| | | |
|---|-------------------|-------------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 15 g in 100 mL |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 15 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:49952-004-01 | 1 in 1 BOX | | |
| 1 | NDC:49952-004-26 | 26 mL in 1 BOTTLE, GLASS | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 04/15/2014 | |

Labeler - Uncle Bill Trading USA Inc. (795709307)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------------|---------|-----------|------------------------|
| Hong Kong Zihua Pharmaceutical Ltd. | | 663989580 | manufacture(49952-004) |