

**ZIHUA EMBROCATION COOLING PAIN RELIEF- camphor menthol methyl salicylate oil**  
**Hong Kong Zihua Pharmaceutical 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.*

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**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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49980-003
<b>Route of Administration</b>	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:49980-003-01	1 in 1 BOX		
1	NDC:49980-003-26	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** - Hong Kong Zihua Pharmaceutical Ltd. (663989580)

### Establishment

Name	Address	ID/FEI	Business Operations
Hong Kong Zihua Pharmaceutical Ltd.		663989580	manufacture(49980-003)

Revised: 4/2014

Hong Kong Zihua Pharmaceutical Ltd.