ZHENWEILONG HUOLUO YOU EXTERNAL ANALGESIC- 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.

Drug Facts

Active Ingredients

Camphor 10%

Menthol 15%

Methyl Salicylate 30%

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.

■ Children under 12 years of age, consult a doctor before using

■ Do not use otherwise than as directed

Inactive ingredients

Dragon's blood (resin), eucalyptus oil, mineral oil, peppermint oil

Package Label

ZHENWEILONG HUOLUO YOU EXTERNAL ANALGESIC

camphor menthol methyl salicylate oil

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49980-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	10 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	30 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
DRAGON'S BLOOD (UNII: M3YJ2C28IC)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49980-001-01	1 in 1 BOX		
1	NDC:49980-001-50	50 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	08/01/2013	

Labeler - Hong Kong Zihua Pharmaceutical Ltd. (663989580)

Establishment

Name	Address	ID/FEI	Business Operations
Hong Kong Zihua Pharmaceutical Ltd.		663989580	manufacture(49980-001)

Revised: 10/2014 Hong Kong Zihua Pharmaceutical Ltd.