# ZHENWEILONG HUOLUO YOU EXTERNAL ANALGESIC- 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 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

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49952-001	
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:49952-001-01	1 in 1 BOX		
1 NDC:49952-001-50	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** - Uncle Bill Trading USA Inc. (795709307)

Establishment				
Name	Address	ID/FEI	Business Operations	
Hong Kong Zihua Pharmaceutical Ltd.		663989580	manufacture(49952-001)	

Revised: 10/2014 Uncle Bill Trading USA Inc.