SHU JIN LU- camphor and menthol spray GUANGXI YULIN 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 FACTS

Active ingredients

Camphor 5.5% Menthol 5.5%

Purposes

External analgesic External analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints due to: simple backache arthritis strains bruises sprains

Warnings

For external use only

Do not use

on wounds on irritated or damaged skin otherwise than as directed

When using this product

avoid contact with the eyes or mucous membranes do not bandage tightly

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
nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs
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 to avoid accidental poisoning.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 3 years of age and older: Spray on the affected area not more than 3 to 4 times daily children under 3 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 tightly closed store at room temperature 15° to 30° C (59° to 86° F)

Inactive ingredients

bicolor artocarpus (Artocarpus styracifolius Pierre) root, cinnamon twigs, dimethyl sulfoxide, futokadsura Kadsura heterocita (Roxb.) Craib stem, fragrant angelica root, gleditsia (Gleditsia sinensis Lam.) fruit, hen's eyes (Ardisia crenata Sims.) Root, Japanese knotweed (Polygonum cuspidatum Siebold Zucc.) root, methyl salicylate, moghania (Moghania philippinensis Merr. Rolfe) root, securidaca (Securidaca inappendiculata Hassk.) herb, sheep's ear (Inula cappa Buch.-Ham. ex D. Don) DC. herb, St. Thomas bean Entada phaseoloides (L.) Merr. Stem, swallowwort Cynanchum paniculatum (Bge.) Kitag. root and rhizome, Vietnamese sophora (Sophora subprostrata Chun T.C. Chen) root, wild pepper Piper wallichii (Miq.) Hand.-Mazz. twigs and leaves, and zedoary rhizome.

Questions or comments?

(888) 221-3496 M-F 9 am to 5 pm you may also report serious side effects to this phone number

SHU JIN LU EXTERNAL ANALGESIC NDC 59321-031-01 2.0 fl oz (60mL)





SHU JIN LU

camphor and menthol spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59321-031	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5.5 g in 100 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.5 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
CINNAMON (UNII: 5S29 HWU6 QB)		
DIMETHYL SULFOXIDE (UNII: YOW8 V9698H)		
ANGELICA DAHURICA ROOT (UNII: 1V63N2S972)		

GLEDITSIA SINENSIS FRUIT (UNII: A6W0J6UO7Q)	
ARDISIA JAPONICA STEM (UNII: Q6CE3213C7)	
POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
ENTADA PHASEOLOIDES LEAF (UNII: W20C93AH7K)	
CHELIDO NIUM MAJUS (UNII: 7E889 U5RNN)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
ZEDO ARY (UNII: 123C43G128)	

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:59321-031- 01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	0 4/0 7/20 11	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/07/2011		

Labeler - GUANGXI YULIN PHARMACEUT ICAL CO LTD (653862581)

Establishment				
Name	Address	ID/FEI	Business Operations	
GUANGXI YULIN PHARMACEUTICAL CO LTD		653862581	manufacture(59321-031)	

Revised: 10/2018 GUANGXI YULIN PHARMACEUTICAL CO LTD