REFINED GOU PI PAIN RELIEVING PLASTER- methyl salicylate, camphor, menthol plaster International Nature Nutraceuticals

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 Listing

Active Ingredients:

Methyl Salicylate: 14.6%...External Analgesic

Camphor: 3.5%....External Analgesic Menthol: 2.3%....External Analgesic

Uses:

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

Warnings:

For external use only

When Using this product:

Avoid contact with the eyes. Do not apply to wounds 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.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

In case swallowed, get medical help or contact a poison control center right away.

Directions:

Adults and children 12 years of age and older: apply one or two plasters to affected area once a day, remove after 8 hours.

Children 2 to 12 years of age and adults with compromised health: use only under the guidance of a doctor

Children under 2 years of age: do not use.

Storage

Store at 15°C to 30°C (59°F to 86°F)

Keep away from heat

Inactive Ingredients

Kaemferia galanga root, ginger, corydalis yanhusuo tuber, paprika, stephania root, impatiens balsamina leaf, natural latex rubber

Packaging



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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51367-020	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	120.8 mg		
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	116 mg		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	116 mg		

Inactive Ingredients			
Ingredient Name	Strength		
KAEMPFERIA GALANGA ROOT (UNII: 7B7U9D12AI)			
GINGER (UNII: C5529G5JPQ)			
CORYDALIS YANHUSUO TUBER (UNII: 0TUP42692Z)			
PAPRIKA (UNII: X72Z47861V)			
STEPHANIA TETRANDRA ROOT (UNII: 48 PS8 1XHK0)			
IMPATIENS BALSAMINA LEAF (UNII: LH9E1X602V)			
NATURAL LATEX RUBBER (UNII: 2LQ0 UUW8 IN)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:51367- 020-04	8 in 1 PACKAGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	05/16/1979	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	05/16/1979		

Labeler - International Nature Nutraceuticals (006106879)

Establishment				
Name	Address	ID/FEI	Business Operations	
Huangshi Hygienic Material Medicine Co., Ltd		527157596	manufacture(51367-020)	

Revised: 7/2017 International Nature Nutraceuticals