

PAIN RELIEF PATCHES PATCHES- dl-camphor l-menthol methyl salicylate patch
Shanghai Aquagel Bio-Plymer 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

For External Use Only

DL-Camphor

1.2%.....Topical
analgesic

L-Menthol

4.0%.....Topical
analgesic

Methyl Salicylate

6.3%.....Topical analgesic

Uses

For temporary relief of minor aches and pains associated with:

Arthritis

Backaches

Sprains

Strains

Bruises

Warnings

For External Use Only

Do not use

other than as directed on wounds, damaged or irritated skin in combination with other external analgesic products, ointments, creams or with a heating pad. in contact with eyes or mucous membranes. if you are allergic to any ingredient in this product. if you have a history of allergic reactions to this or similar products

Stop Use and ask a doctor if

rash, itching or excessive skin irritation develops

condition worsens

symptoms persist for more than 7 days

if symptoms subside and then reappear within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

Directions

Adults and children 12 years of age and over: Clean and dry the affected area. Remove patch from film

backing. Adhere

to area for no more than 8 hours at a time, not more than 3 times per day, and for no more than 7 days continuously.

Children under 12 years of age: Consult a doctor before use.

Other information

Store in a cool dry place. Avoid direct sunlight.

Inactive ingredients Ammonium Stearate, Calcium Carbonate, Glyceryl Abietate, Isopropyl Myristate, Natural

Rubber, Polybutene, Polyisobutylene, Propylene Carbonate, Styrene Copolymer, YS Resin, Zinc Oxide



PAIN RELIEFPATCHES PATCHES			
dl-camphor l-menthol methyl salicylate patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53043-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	1.2 mL in 100 mL	
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	4 mL in 100 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	6.3 mL in 100 mL	

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM STEARATE (UNII: 37899330TZ)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
GLYCERYL ABIETATE (UNII: 2F22LY70Q1)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
STYRENE (UNII: 44LJ2U959V)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53043-001-01	20 in 1 CARTON		
1		24 mL in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2012	

Labeler - Shanghai Aquagel Bio-Polymer Co., Ltd (421199544)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Aquagel Bio-Polymer Co., Ltd		421199544	manufacture(53043-001)

Revised: 8/2012

Shanghai Aquagel Bio-Polymer Co., Ltd