PAIN RELIEF PATCHES- camphor, menthol, methyl salicylate patch Chain Drug Consortium, LLC

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.

Medicated Pain Relief Patch Topical Analgesic

Active Ingredients

Active Ingredients Purpose

Camphor 3.1%Topical Analgesic

Menthol 6.0%Topical Analgesic

Methyl Salicylate 10.0%Topical Analgesic

For External Use Only

Allergy alert: If prone to allergic reaction from asprin or salicylates, consult a doctor before use

Do not use:

- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredients of this product

When using this product

- Use only as directed
- Avoid contact with eyes, mucous membranes or rashes
- Do not bandage tighly
- Do not use at the same time as other topical analgesics
- Dispose of used patch in manner that keeps product away from childrens and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

QUESTIONS

Customer Care Help Line **248-449-9300** www.qualitychoice.com

Stop use and consult a doctor

- If rash, itching or excessive skin irritation develops
- If condition worsens
- if symptoms last more than 7 days or clear up and occur again with a few days

Keep out of reach of children

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

Uses

For temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, and bruises.

Directions

Adults and children 12 years of age and over: Clean and dry affected area. Remove patch from film, apply to affected area not more than 3 to 4 times daily. Remove patch from the skin after at most, 8-hour application.

Children under 12 years of age: consult physician.

Inactive Ingredients

Hydrogenated Poly, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Petroleum, Styrene / Isoprene Copolymer

Indication and Usage

For temporary relief of minor aches and pains.

Pain Relief Patch Label



Other Information: Store in clean, dy place outside of direct sunlight. Protect from excessive moisture.

PAIN RELIEF PATCHES

camphor, menthol, methyl salicylate patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.1 g in 100 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	6 g in 100 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
HYDRO GENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDRO XYPHENYL)PRO PIO NATE) (UNII: 255PIF62MS)	
LIQUID PETROLEUM (UNII: 6ZAE7X688J)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	

Product Characteristics			
Color		Score	
Shape	SQUARE	Size	
Flavor		Imprint Code	
Contains			

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68016-071-60	60 in 1 BOX	06/01/2017	
	1	9 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2017	

Labeler - Chain Drug Consortium, LLC (101668460)

Establishment				
Name	Address	ID/FEI	Business Operations	
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(68016-071)	

Revised: 10/2017 Chain Drug Consortium, LLC