

EXTRA STRENGTH COLD-HOT MEDICATED PATCHES- menthol patch
Cardinal Health, 110 dba LEADER

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.

Extra Strength Cold-Hot Medicated Patches

ACTIVE INGREDIENT

Active Ingredient	Purpose
Menthol 5%.....	Topical
Analgesic	

INACTIVE INGREDIENT

CMC, Dihydroxy aluminum Aminoacetate, Glycerin, Kaolin, Mineral Oil, Methylparaben, Petrolatum, Polyacrylic Acid, Polysorbate 80, Propylene Glycol, Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

KEEP OUT OF REACH OF CHILDREN

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

INDICATIONS & USAGE

Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ bursitis ■ tendonitis ■ muscle strains ■ muscle sprains ■ bruises ■ cramps

WARNINGS

For External Use Only.

DOSAGE & ADMINISTRATION

Adults and children 12 years of age and over: Carefully remove backing from patch. Apply sticky side of patch to affected area. Wear one patch up to 8 hours. Repeat as necessary, but no more than 4 times daily. Reseal pouch after opening. Discard patch after single use. Children under 12 years of age: consult a physician.

PURPOSE

Topical Analgesic

When using this product

Use only as directed ■ Don't bandage tightly or use with heating pad
■ Avoid contact with eyes and mucous membranes ■ Don't apply to wounds or damaged skin.

Stop use and ask a doctor

If condition worsens ■ If redness is present ■ If irritation develops
■ If symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breastfeeding

ask a health professional before use.

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0367
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g

Inactive Ingredients

Ingredient Name	Strength
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0367-1	5 in 1 BOX	01/01/2019	
1		1 in 1 POUCH; 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	01/01/2019	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(70000-0367)

Revised: 1/2023

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