BACK AND LARGE EXTRA STRENGTH COLD-HOT MEDICATED PATCHES- menthol patch
QUALITY CHOICE (Chain Drug Marketing Association)

Back and Large 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.

BACK AND LARGE EXTRA STRENGTH COLD-HOT MEDICATED

PATCHES

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-294
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**
PETROLATUM (UNII: 4T6H12BN9U)	
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: 05I15JNI2J)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63868-294-05	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 Drug	M017	01/01/2019	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(63868-294)

Establishment

Name	Address	ID/FEI	Business Operations
Beijing HKKY Medical		544434817	manufacture(63868-294)

Revised: 12/2024 QUALITY CHOICE (Chain Drug Marketing Association)