

EXTRA LARGE COOL AND HEAT PATCH- menthol patch
Walgreen Company

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 Large Cool and Heat Patch

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

Do not use on infants. If swallowed, get medical help or contact a Poison Control Center (800-222-1222) right away.

INDICATIONS & USAGE

For temporary relief of minor aches and pains of muscles and joints: arthritis, simple backache, bursitis, tendonitis, muscle strains, muscle sprains, bruises and cramps.

WARNINGS

For External Use Only.

DOSAGE & ADMINISTRATION

Adults and children over 12 years: 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 3 times daily. Reseal pouch after opening.

Children 12 years or younger: Consult a physician.

PURPOSE

Topical Analgesic

When using this product

When using this product ■ Use only as directed ■ Rare cases of serious burns have been reported with products of this type ■ Don't bandage tightly or use with heating pad ■ Avoid contact with eyes and mucous membranes ■ Don't apply to wounds or damaged skin ■ Do not use at the same time as other topical analgesics.

Stop use and ask a doctor

■ Condition worsens ■ Redness is present ■ Irritation develops ■ Symptoms persist for more than 7 days or clear up and occur again within a few days ■ You experience signs of skin injury, such as pain, swelling, or blistering where the product was applied.

If pregnant or breastfeeding

ask a health professional before use.

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9905
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9905-03	3 in 1 BOX	01/01/2020	
1		9 g 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	01/01/2020	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(0363-9905)

Revised: 1/2023

Walgreen Company