

**HOT AND COLD MEDICATED 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.*

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**Cool n' Heat Medicated Patch Large**

**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

**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 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 4 times daily. Reseal pouch after opening.

Children 12 years or younger: 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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-9520
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>DIHYDROXYALUMINUM AMINOACETATE</b> (UNII: DO250MG0W6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>POLYACRYLIC ACID (250000 MW)</b> (UNII: 9G2MAD7J6W)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9520-05	5 in 1 BOX	01/01/2018	
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	01/01/2018	

**Labeler** - Walgreen Company (008965063)

## Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(0363-9520)

Revised: 1/2023

Walgreen Company