

RITE AID HOT AND COLD BACK PATCH- menthol patch

Rite Aid Corporation

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.

Rite Aid Hot and Cold Back Patch

Active Ingredient

Menthol 5%

Purpose

Topical anesthetic

Use

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

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 consult a doctor if

- o condition worsens
- o redness is present
- o irritation develops
- o symptoms persist for more than 7 days or clear up and occur again within a few days
- o you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children and pets

Do not use on infants. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

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 3 times daily. Discard patch after single use. Reseal pouch after opening. Children under 12 years of age: consult a physician.

Other information

Store at room temperature, not to exceed 86°F (30°C).

Inactive Ingredient

carboxymethylcellulose sodium, dihydroxyaluminum aminoacetate, glycerin, iodopropynyl butylcarbamate, kaolin, mineral oil, petrolatum, phenoxyethanol, polyacrylic acid, polysorbate 80, povidone, propylene glycol, sodium polyacrylate, tartaric acid, titanium dioxide, water, 3-(2-ethylhexyloxy)propane-1,2-diol

Rite Aid Hot and Cold Back Patch

MINERAL OIL (UNII: T5L8T28FGP)
WATER (UNII: 059QF0KO0R)
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)
3-IODO-2-PROPYNOL (UNII: A477M4X26N)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)
GLYCERIN (UNII: PDC6A3C0OX)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
KAOLIN (UNII: 24H4NWX5CO)
PETROLATUM (UNII: 4T6H12BN9U)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-9991-3	3 in 1 CARTON	03/01/2023	
1		1 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	03/01/2023	

Labeler - Rite Aid Corporation (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.		529128763	manufacture(11822-9991)

Revised: 3/2023

Rite Aid Corporation