

CVS COLD HOT MEDICATED- menthol patch

CVS Pharmacy Inc.

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.

Drug Facts

Active Ingredient	Purpose
Menthol 5%	Topical Analgesic

Uses

Temporarily relieves minor pain associated with:

- Arthritis
- Simple Backache
- Bursitis
- Tendonitis
- Muscle Strains
- Bruises
- Cramps

For external use only

When using this product

- Use only as directed
- Do not bandage tightly or use with a heating pad
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds or damaged skin

Stop use and ask a doctor if

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Redness is present
- Skin irritation develops

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: adults and children 12 years of age and older

- Peel off protective backing and apply sticky side to affected area
- Carefully remove backing from patch
- Should be used up to 8 hours
- Should be used no more than 3 times a day
- Children under 12 years of age consult a doctor

Other Information

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

Inactive Ingredients:

1,3 butylene glycol, aloe vera (powder), dibutylhydroxytoluene, disodium edetate, d-sorbital solution,

glycerine, kaolin, light liquid paraffin, magnesium aluminum hydrate, methacrylic acid butylacrylate copolymer, methyl parahydroxybenzoate, polysorbate 80, purified water, sodium methaphosphate, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide, tocopherol acetate

DISTRIBUTED BY:

CVS PHARMACY, INC.

ONE CVS DRIVE

WOONSOCKET, RI 02895 USA



CVS COLD HOT MEDICATED

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-821
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
1,3-BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-821-05	5 in 1 BOX		
1		.05 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/14/2013	

Labeler - CVS Pharmacy Inc. (062312574)

Revised: 10/2013

CVS Pharmacy Inc.