

QC COLD AND HOT PAIN RELIEF- menthol patch
CHAIN DRUG MARKETING ASSOCIATION 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

Menthol 5.0%

Purpose

Topical Analgesic

Uses

temporarily relieves minor pain associated with

- arthritis
- simple backache
- bursitis
- tendonitis
- muscle strains
- sprains
- bruises
- cramps

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with eyes and mucous membranes
- do not bandage tightly or use with a heating pad
- do not apply to wounds or damaged skin, broken or irritated skin

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	400 mg

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-012-05	1 in 1 CARTON		
1		5 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/12/2011	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

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