

COLD AND HOT MEDICATED PAIN RELIEF SMALL - menthol patch
Valu Merchandisers Company, 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%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain associated with:

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

Warnings

For external use only

When using this product

- use only as directed
- do not bandage tightly or use with 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
- 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.

For use on children 12 years or younger consult a doctor. Do not use on infants. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and children over 12 years:

- carefully remove backing from patch
- apply sticky side of patch to affected area
- repeat as necessary, but no more than 4 times daily

Inactive ingredients

2-ethylhexyl acrylate, acrylic acid, aluminium hydroxide, carboxymethylcellulose sodium, glycerin, isopropyl myristate, methyl acrylate, nonoxynol-30, polyacrylic acid, polysorbate 80, purified water, sodium polyacrylate, sorbitan sesquioleate, starch, talc, tartaric acid, titanium oxide

package label

Best Choice Cold and Hot Small Medicated Patch



COLD AND HOT MEDICATED PAIN RELIEF SMALL			
menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-950
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)	
WATER (UNII: 059QF0KO0R)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-950-05	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 - Valu Merchandisers Company, Inc. (868703513)

Revised: 9/2011

Valu Merchandisers Company, Inc.