COLD AND HOT PAIN RELIEF - menthol patch Navarro Discount Pharmacies, LLC

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

Warnings

For external use only

When using this product

- use only as directed
- do not bandage tightly
- do not use a heating pad
- avoid contact with eyes and mucous membrane
- do not apply to wounds or damaged skin
- do not use if you are allergic to any ingredients of this product

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
- 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 over 12 years:

- Remove backing from patch by grasping both ends firmly
- Carefully remove backing from patch
- Apply one patch to affected area
- Repeat as necessary, but no more than 4 times daily

Children under 12 years of age: Ask a doctor

Other information

store at room temperature

Inactive ingredients

aluminium glycinate, 1,3-butylene glycol, carboxymethylcellulose sodium, concentrated glycerin, diethylene glycol monoethyl ether, disodium edetate, methyl parahydroxybenzoate, polyacrylic acid solution, polysorbate 80, propyl parahydroxybenzoate, purified water, tartaric acid, titanium dioxide

package label



COLD AND HOT PAIN RELIEF

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59970-054	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
ı	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	400 mg

Inactive Ingredients		
Ingredient Name	Strength	
DIHYDRO XYALUMINUM AMINO ACETATE (UNII: DO 250 MG0 W6)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8 X02B)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
METHYLPARABEN (UNII: A218 C7H19 T)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
TARTARIC ACID (UNII: W48881119H)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:59970-054-05	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	08/01/2012		

Labeler - Navarro Discount Pharmacies,LLC (094930963)

Revised: 8/2012 Navarro Discount Pharmacies,LLC