

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 glycolmonoethyl Ether, disodium edetate, methyl parahydroxybenzoate, polyacrylic acid solution, polysorbate 80, propyl parahydroxybenzoate, purified water, sodium polyacrylate, tartaric acid, titanium dioxide

package label

Cold and Hot Pain Relief Patch

PRIMA INFORMACIÓN EN ESPAÑOL LEA EL INSERTO

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*This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Icy Hot® Patch.
*Este producto no es fabricado ni distribuido por Chatterm, Inc., propietario de la marca registrada, Icy Hot® Patch.

EXTRA STRENGTH / EXTRA POTENTE
COLD & HOT
FRÍO Y CALIENTE
MEDICATED PATCH / PARCHES MEDICADOS
MENTHOL 5% / MENTOL 5%

EXTRA STRENGTH EXTRA POTENTE
NDC 4597717-03063

8 HOURS / 8 HORAS

5 LARGE PATCHES / 5 PARCHES GRANDES
3.93" X 8.26"
10CM X 21CM EACH

BACK & LARGE AREAS
ESPALDA Y AREAS GRANDES

Pain Relieving Ointment on a Breathable Adhesive Pad
Unguento para Aliviar el Dolor en una Adhesiva Impermeable Transpirable
Contiene 5 parches en una bolsa resealable

PRIMA INFORMACIÓN EN ESPAÑOL LEA EL INSERTO

COLD AND HOT PAIN RELIEF

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59970-080
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
DIHYDROXYALUMINUM AMINO ACETATE (UNII: DO250MG0W6)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
TARTARIC ACID (UNII: W48881I19H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59970-080-05	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	08/15/2012	

Labeler - Navarro Discount Pharmacies,LLC (094930963)

Revised: 9/2011

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