

MEIJER EXTRA STRENGTH COLD AND HOT MEDICATED - menthol patch

Meijer

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
- muscle sprains
- bruises
- cramps

Warnings 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

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

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

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°F (30°C)

Inactive ingredients aloe vera, aluminum hydroxide, BHT, castor oil, disodium edetate, gelatin, glycerin, isopropyl myristate, kaolin, magnesium aluminometasilicate, methylparaben, polyethylene glycol monostearate, polysorbate 80, polyvinyl alcohol, polyvinyl pyrrolidone, purified water, sodium

polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate. Release Liner: polypropylene, non-woven material: polyester non-woven fabric.

Distributed By:

Meijer Distribution, Inc.

2929 Walker Ave

Grand Rapids, MI 49544



MEIJER EXTRA STRENGTH COLD AND HOT MEDICATED

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-215
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	750 mg

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GELATIN (UNII: 2G86QN327L)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
KAOLIN (UNII: 24H4NWX5CO)
METHYLPARABEN (UNII: A2I8C7HI9T)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POLYVINYL ALCOHOL (UNII: 532B59J990)
WATER (UNII: 059QF0K00R)
TARTARIC ACID (UNII: W4888119H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-215-05	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	06/30/2013	

Labeler - Meijer (006959555)