

**MAJOR EXTRA STRENGTH COLD AND HOT PAIN RELIEF THERAPY- menthol patch**  
**Major Pharmaceuticals**

*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.*

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**Major Cold & Hot patch, 5ct in resealable pouch (69401)**

<b>Active ingredient</b>	<b>Purpose</b>
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 skins

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**

- **adults and children 12 years:**
- □remove backing from patch by grasping both ends firmly and gently pulling until backing separates in middle
- carefully remove backing from patch
- apply one patch to affected area
- wear one patch up to 8 hours
- repeat as necessary, but no more than 4 times daily

**□children 12 years or younger:**

- □consult a doctor

## Other information

- store at room temperature, not to exceed 86°F (30°C)

**Inactive ingredients** 1,3-butylene glycol, aloe vera, BHT, d-sorbitol, disodium edetate, gelatin, glycerin, kaolin, liquid paraffin, magnesium aluminum hydrate, methacrylic acid butylacrylate copolymer, methyl parahydroxybenzoate, polysorbate 80, purified water, sodium metaphosphate, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide, tocopherol acetate

## Distributed By:

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Livonia, MI 48150  
Made in Korea



## MAJOR EXTRA STRENGTH COLD AND HOT PAIN RELIEF THERAPY

menthol patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-5694
<b>Route of Administration</b>	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
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SORBITOL (UNII: 506T60A25R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MAGALDRATE (UNII: 6V88E24N5T)	
METHYLPARABEN (UNII: A2I8C7H9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	
SODIUM METAPHOSPHATE (UNII: 532IUT7IRV)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5694-01	1 in 1 PACKAGE	06/30/2013	
1		5 in 1 POUCH; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/30/2013	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 12/2017

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