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.

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

W**hen 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 seperates 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-butlene 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:

Major Pharmaceuticals

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Suite 233

Livonia, MI 48150

Made in Korea

MAJOR EXTRA STRENGTH COLD AND HOT PAIN RELIEF THERAPY

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-5694
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
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: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM METAPHOSPHATE (UNII: 532IUT7IRV)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	
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	02/03/2017	
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: 2/2017 Major Pharmaceuticals