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.

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

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 of age and older
- carefully peel off protective backing from patch and apply sticky side to affected area
- may be worn up to 8 hours
- do not use 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 1,3-butlene glycol, aloe vera (powder), metacrylic acid butlacrylate copolymer, dibutylhydroxytoluene, disodium edetate, d-sorbitol solution, gelatin, glycerine, kaolin, light liquid paraffin, magnesium aluminium hydrate, methyl parahydroxybenzoate, polysorbate 80, purified water, sodium metaphosphate, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium oxide,

tocopherol acetate

Distributed By:

Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150

Made in Korea

MAJOR EXTRA STRENGTH COLD AND HOT PAIN RELIEF THERAPY

menthol patch

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:0904-5694
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (MENTHOL)	MENTHOL	750 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL	

ALOE VERA LEAF	
EDETATE DISODIUM	
GELATIN	
GLYCERIN	
KAOLIN	
LIGHT MINERAL OIL	
METHYLPARABEN	
POLYSORBATE 80	
WATER	
SODIUM POLYMETAPHOSPHATE	
SORBITAN MONOOLEATE	
TARTARIC ACID	
TITANIUM DIOXIDE	
ALPHA-TOCOPHEROL ACETATE	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5694-01	1 in 1 PACKAGE		
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 - Major Pharmaceuticals (191427277)

Revised: 6/2013 Major Pharmaceuticals