

CVS COLD AND HOT MEDICATED XL- menthol patch
CVS PHARMACY, INC.

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.

CVS Cold & Hot Medicated XL Patch, 3ct (NBE Icyhot) 98104

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 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
- redness is present
- skin 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. Do not use on infants. If swallowed, get medical help or contact a Poison Control Center immediately

Directions

adults and children over 12 years:

- 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:

□consult a doctor

Other information

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

Inactive ingredients

aloe barbadensis leaf juice, aluminum hydroxide, BHT, castor oil, disodium edetate, gelatin, glycerin, isopropyl myristate, kanolin, magnesium aluminate metasilicate, methylparaben, peg-40 stearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate

release liner: polyethylene, non-woven material: polyester non-woven fabric.

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

www.cvs.com

1-800-shop-CVS

Made in Korea



CVS COLD AND HOT MEDICATED XL

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-981
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)	
CASTOR OIL (UNII: D5340Y2I9G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
WATER (UNII: 059QF0K00R)	
TARTARIC ACID (UNII: W48881I19H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-981-04	1 in 1 CARTON	11/11/2010	
1		3 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	11/11/2010	

Labeler - CVS PHARMACY, INC. (062312574)

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment			
Name	Address	ID/FEI	Business Operations
SINSIN PHARMACEUTICAL CO., LTD.		687867143	manufacture(59779-981)

