

CORALITE EXTRA STRENGTH COOL AND HOT- menthol patch

United Exchange Corp.

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

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

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

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
- 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 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 aluminum metasilicate, methylparaben, polyethylene glycol monostearate, polysorbate 80, polyvinyl alcohol, polyvinylpyrrolidone, purified water, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate, Release Liner: polypropylene, non-woven material: polyester non-woven fabric

DISTRIBUTED BY:
 UNITED EXCHANGE CORP.
 17211 VALLEY VIEW AVE.
 CERRITOS, CA 90703 USA
 MADE IN KOREA



CORALITE EXTRA STRENGTH COOL AND HOT

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-145
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

CASTOR OIL (UNII: D5340Y2I9G)
GELATIN (UNII: 2G86QN327L)
GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
KAOLIN (UNII: 24H4NWX5CO)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
METHYLPARABEN (UNII: A2I8C7HI9T)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POLYVINYL ALCOHOL (UNII: 532B59J990)
WATER (UNII: 059QF0KO0R)
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)
TARTARIC ACID (UNII: W4888I119H)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-145-05	5 in 1 BOX		
1		1 g in 1 PATCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/30/2014	

Labeler - United Exchange Corp. (840130579)