CORALITE COLD 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 aches and pains of muscles and joints due to:

- arthritis
- simple backache
- bursitis
- tendonitis
- 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 mebranes
- 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 Poision 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 under 12 years of age**: consult a doctor

Other Information

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

Inactive ingredients

aloe vera gel, BHT, castor oil, concentrated glycerin, disodium edetate hydrate, dried aluminum hydroxide gel, gelatin, isopropyl myristate, kaolin, magnesium aluminosilicate, methylparaben, PEG, monostearate, polysorbate 80, polyvinyl alcohol, purified water, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate

DISTRIBUTED BY:

UNITED EXCHANGE CORP.

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CERRITOS, CA 90703 USA

CORALITE COLD AND HOT

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-153
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
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:65923-153-02	2 in 1 POUCH	07/13/2017	
1		1 g in 1 PATCH; 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	12/16/2013	

Labeler - United Exchange Corp. (840130579)

Revised: 7/2017 United Exchange Corp.