

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.

Coralite Pain Relief menthol Patch 2 ct. 90150 (2019)

Drug Facts

Active ingredient Purpose

Menthol 5%.....Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you have

- redness over the affected area

When using this product

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly
- discontinue use at least 1 hour before a bath or shower
- do not use immediately after a bath or shower

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

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 (1-800-222-1222) right away.

Directions

- open pouch and remove patch
- carefully peel off protective backing and apply sticky side to affected area
- adults and children 12 years of age and older:
- do not wear patch for more than 8 hours

- apply to affected area no more than 3 times daily
- children under 12 years of age: consult a doctor

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive ingredients

alcohol, aluminum glycinate, glycerin, kaolin, methylparaben, polysorbate 80, propylparaben, purified water, sodium polyacrylate, sorbitan monooleate, tartaric acid, titanium dioxide

Distributed by:

United Exchange Corp.
 Cypress, CA 90630 USA
 Made in China



CORALITE COLD AND HOT			
menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-205

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W48881119H)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
KAOLIN (UNII: 24H4NWX5CO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-205-02	2 in 1 POUCH	04/04/2019	
1		1 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	04/04/2019	

Labeler - United Exchange Corp. (840130579)

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United Exchange Corp.