# 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.

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### **Active ingredient Purpose**

Menthol 7.5%......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 or at the same time with other topical analgesic
- 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

- conditions 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

aluminum silicate, butylated hydroxytoluene, glyceryl rosinate, lanolin, natural rubber, polyisobutylene (85000 MW), styrene-isoprene-styrene block copolymer, titanium dioxide, zinc oxide

### 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:65923-214
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	210 mg		

Inactive Ingredients			
Ingredient Name	Strength		
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (UNII: K7S96QM8DV)			
LANOLIN (UNII: 7EV65EAW6H)			
NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
ZINC OXIDE (UNII: SOI2LOH54Z)			
POLYISOBUTYLENE (85000 MW) (UNII: 7X53O5S2ZY)			
ALUMINUM SILICATE (UNII: T1FAD4SS2M)			
GLYCERYL ROSINATE (UNII: SD112V492J)			

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:65923-214- 01	1 in 1 POUCH; Type 0: Not a Combination Product	09/26/2023		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	09/26/2023			

## Labeler - United Exchange Corp. (840130579)

Revised: 9/2023 United Exchange Corp.