

CORALITE COLD AND HOT MEDICATED- menthol patch
United Exchange Corporation

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 Cold & Hot Medicated Patch 1ct Large (90151,2020)

Active ingredient Purpose

Menthol 5%.....Topical Analgesic

Uses

- temporarily relives minor aches and pains of muscles and joints associated with:
- simple backache
- arthritis
- strains
- brusies
- 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

Stope 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 removew patch

CORALITE COLD AND HOT MEDICATED

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-154
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
TARTARIC ACID (UNII: W4888I119H)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-154-01	1 in 1 POUCH	10/22/2018	
1		5 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	10/22/2018	

Labeler - United Exchange Corporation (840130579)

