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

- 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

Questions or comments?

Call 1-800-814-8028 Monday-Friday 9AM-5PM (PST)

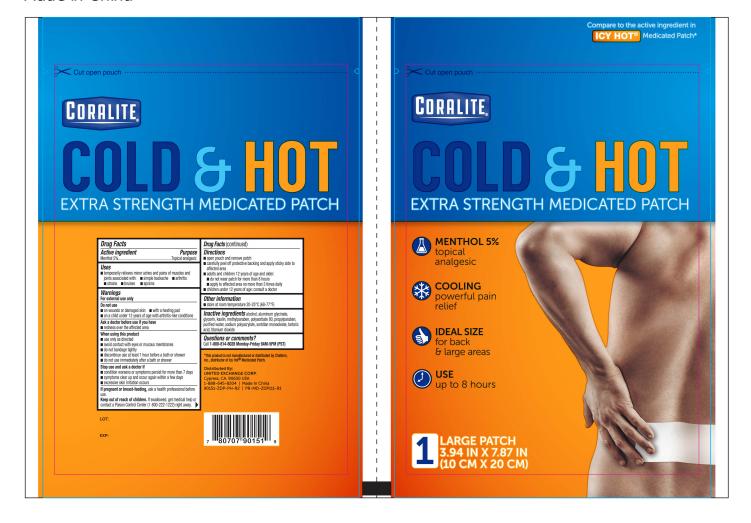
Distributed By:

UNITED EXCHANGE CORP.

Cypress, CA. 90630 USA

1-800-814-8028

Made in China



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 MENTHOL (UNII: L7T10EIP3A) (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: 05I15JNI2J)			
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: Z8IX2SC10H)			
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)			

ı	Packaging					
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:65923-154-	1 in 1 POUCH	10/22/2018			
	L	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			
	part348	10/22/2018			