FAMILY CARE PAIN RELIEF- menthol stick 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 Pain Relief Stick 1.75oz (90120, 2018)

Active ingredient Purpose

Menthol 2%.....Topical analgesic

Uses

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

Warnings

For external use only

Allergy alert: If prone to allergic reaction from aspirin or slicylates, consult a doctor before use.

Do not use

- on wounds or damaged skin
- with a heating pad
- if you are allergic to any ingredients of this product
- on a child under 12 years of age with arthritis-like conditions

Distributed By:

UNITED EXCHANGE CORPORATION

Cypress, CA. 90630 USA | 1-888-645-8204 | Made in China

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, mucous membranes or rashes
- 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

- redness is present or irritation or rash develops
- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

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

- adults and children 12 years of age and older:
- clean and dry affected area
- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily
- children under 12 years of age: consult a doctor
- store at room temperature 20-25°C (68-77°F)
- protect from excessive heat

Inactive ingredients alcohol, hydrogenated castor oil, methyl salicylate, peg-150 distearate, propylene glycol, purified water, sodium stearate





Drug Facts (continued) Ask a doctor before use if you have redness over the affected When using this product use only as directed

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FAMILY CARE PAIN RELIEF

menthol stick

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:65923-119

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) **MENTHOL** 20 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
METHYL SALICYLATE (UNII: LAV5U5022Y)		

ALCOHOL (UNII: 3K9958V90M)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	

l	Packaging						
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
ı	1 NDC:65923-119-01	0.02 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2018				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	10/30/2018			

Labeler - United Exchange Corporation (840130579)

Revised: 10/2018 United Exchange Corporation