CORALITE PAIN RELIEF- menthol capsaicin 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.

Active Ingredients Purpose

Menthol 30 mg...... Topical analgesic

Capsaicin 8.3 mg...... Topical analgesic

Uses

Temporarily relieves minor pain associated with:

- arthritis
- simple backache
- bursitis
- tendonitis
- muscle strains
- bruises
- cramps

Warnings

For external use only

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged skin

Stop use and ask a doctor if:

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

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 right away.

Directions

- Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 12 year of age: do not use, consult a doctor
- For easy applications: partially peel back protectice film and apply exposed patch to site of pain.
- Carefully remove remaining film while pressing patch to skin for secure adhesion.

Inactive ingredients

laloe vera gel, BHT, castor oil, concentrated glycerin, disodium edetate hydrate, dried aluminum hydroxide gel, gelatin, isopropyl myristate,

kaolin, magnesium aluminosilicate, methylparaben, PEG monostearate, polysorbate 80, polyvinyl alcohol, purifed water, PVP, sodium

polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate

DISTRIBUTED BY:

UNITED EXCHNAGE CORP.

17211 VALLEY VIEW AVE.

CERRITOS, CA 90703 USA



CORALITE PAIN RELIEF

menthol capsaicin patch

Product Information	oduct Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-152		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	30 mg in 1 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	8.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
CASTOR OIL (UNII: D5340 Y2I9 G)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
ALMASILATE (UNII: OZQ8O62H53)	
METHYLPARABEN (UNII: A218 C7HI9 T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W48881119 H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65923-152-02	2 in 1 POUCH	07/13/2017		
1		1 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	12/12/2013		

Labeler - United Exchange Corp. (840130579)

Revised: 7/2017 United Exchange Corp.