CORALITE EXTRA STRENGTH PAIN RELIEF SLEEVE KNEE- 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.

Coralite Sleeve Patch, Knee 90121 ZDP

Active ingredient Purpose

Menthol 16.0%......Topical Analgesic Patch

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
- 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 the eyes, mucous membranes or rashes
- do not bandage tightly over sleeve or use with a heating pad
- 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

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- redness is present or irritation or rash 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 (1-800-222-1222) right away

Directions

- adults and children 12 years of age and older:
- open pouch and remove sleeve

- remove plastic insert and discard
- pull sleeve onto knee, large ankles or elbows until the colored (medicated) section of the sleeve is positioned directly over the affected area. Sleeve should feel snug, but not tight. **Note:** the drawings should help you understand how to do this.
- apply one sleeve to affected area no more than 3 times daily
- do not wear sleeve for more than 8 hours
- children under 12 years of age: consult a doctor

Other information

• store at room temperature 20-25°C (68-77°F)

Inative ingredients

carbomer 940, ethanol, ethylparaben, glycerol, propylene glycol, purified water, trolamine

Distributed by:

United Exchange Corp.

Cypress, CA 90630 USA

Made in China



CORALITE EXTRA STRENGTH PAIN RELIEF SLEEVE KNEE

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-121	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	336 mg	

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 903K93S3TK)			
CARBOMER 940 (UNII: 4Q93RCW27E)			

ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ETHYLPARABEN (UNII: 14255EXE39)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-121- 01	1 in 1 BOX	02/10/2016	
1		1 in 1 POUCH; 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	02/10/2016	

Labeler - United Exchange Corp. (840130579)

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