

**CORALITE PAIN RELIEF HOT- menthol and capsaicin 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 Pain Relief Hot Patch 2ct (90152, 2021)

Drug Facts

Active ingredient Purpose

Capsicum extract 0.17 mg as Capsaicin.....Topical analgesic

Menthol 30 mg.....Topical analgesic

Uses

temporarily relieves minor pain of muscles and joints associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises

Warnings

For external use only

Allergy alert: Do not use if you are allergic to capsicum, chili peppers, or any ingredients in this product.

Do not use

- on wounds or damaged skin
- with a heating pad

When using this product

- use only as directed
- avoid contact with the 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

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

- adults and children 18 years of age and older:
- clean and dry affected area
- remove patch from film
- apply to affected area not more than 3 to 4 times daily
- removed patch from the skin after 8 hours application
- children under 12 years of age: ask a doctor

Other information

- store at room temperature 20-25°C (68-77°F)
- avoid storing product in direct sunlight
- protect product from excessive moisture

Inactive ingredients alcohol, aluminum glycinate, glycerin, kalin, 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)

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CORALITE

PAIN RELIEF

EXTRA STRENGTH HOT PATCH

Drug Facts Active ingredients Capsicum extract 0.17 mg as Capsaicin Topical analgesic Menthol 30 mg Topical analgesic	Purpose Temporarily relieves minor pain of muscles and joints associated with: ■ arthritis ■ simple backache ■ strains ■ sprains ■ bruises
Uses Temporarily relieves minor pain of muscles and joints associated with: ■ arthritis ■ simple backache ■ strains ■ sprains ■ bruises	Warnings For external use only Allergy alert: Do not use if you are allergic to capsaicin, chili peppers, or any ingredients in this product. Do not use ■ on wounds or damaged skin ■ with a heating pad
When using this product ■ use only as directed ■ avoid contact with the 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	Directions ■ adults and children 12 years of age and older: ■ clean and dry affected area ■ remove patch from film ■ apply to affected area not more than 3 to 4 times daily ■ remove patch from the skin after 8 hours application ■ children under 12 years of age: ask a doctor
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 7 80707 90152 6	Questions or comments? Call 1-888-645-8204 Monday-Friday 9AM-5PM (PST)
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PAIN RELIEF

EXTRA STRENGTH HOT PATCH

-  **CAPSICUM EXTRACT 0.17 mg AS CAPSAICIN / MENTHOL 30 mg**
(Topical Analgesics)
-  **WARMING**
powerful pain relief
-  **IDEAL SIZE**
for arm, neck, leg & small areas
-  **USE**
up to 8 hours

2 SMALL PATCHES
3.15 IN X 4.72 IN
(8 CM X 12 CM) EACH



CORALITE PAIN RELIEF HOT

menthol and capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-146
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	0.83 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
TARTARIC ACID (UNII: W4888I119H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05I15JNI2J)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
KAOLIN (UNII: 24H4NWX5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-146-02	2 in 1 POUCH	10/23/2018	
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	10/23/2018	

