

## **CAREONE COLD AND HOT- menthol patch**

**American Sales Company**

*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.*

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### **Careone Cold & Hot Medicated Patch 5ct (Large) ZDP 2020**

#### **Active ingredient Purpose**

Menthol 5%.....Topical analgesic

#### **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
- 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

##### **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
- 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 remove 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

Distributed by:

Foodhold U.S.A., LLC



## CAREONE COLD AND HOT

menthol patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-181
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.05 mg

## Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
KAOLIN (UNII: 24H4NWX5CO)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-181-05	1 in 1 BOX	10/28/2019	
1		5 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	10/28/2019	

**Labeler** - American Sales Company (809183973)

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