

## **CAREONE EXTRA STRENGTH 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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### **Active ingredient**

### **Purpose**

Menthol 5%..... 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
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away

### **Directions**

#### **adults and children over 12 years :**

- remove backing from patch by grasping both ends firmly and gently pulling until backing separates in middle
- carefully remove backing from patch
- apply one patch to affected area
- wear one patch up to 8 hours
- repeat as necessary, but no more than 4 times daily

**children 12 years or younger:** ☐consult a doctor

### **Other information**

- store at room temperature, not to exceed 86°F (30°C)

### **Inactive ingredients**

aloe vera, aluminum hydroxide, BHT, castor oil, disodium edetate, gelatin, glycerin, isopropyl myristate, kaolin, magnesium aluminum metasilicate, methylparaben, polyethylene glycol monostearate, polysorbate 80, polyvinyl alcohol, polyvinyl pyrrolidone, purified water, sodium polyacrylate, tartaric acid, titanium dioxide, tocopherol acetate. Release Liner: polypropylene, non-woven material: polyester non-woven fabric

Distributed by:

Foodhold U.S.A., LLC

Landover, MD 20785

Made in Korea



## CAREONE EXTRA STRENGTH COLD AND HOT

menthol patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-871
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CASTOR OIL (UNII: D5340Y2I9G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TARTARIC ACID (UNII: W4888119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-871-05	5 in 1 CARTON	05/10/2017	
1		1 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	06/16/2014	

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

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American Sales Company