

**COLD AND HOT MEDICATED- menthol patch**  
**UNIVERSAL DISTRIBUTION CENTER, LLC**

**5% Menthol Pain Relief Patch (2 Patches/Pouch) NDC: 52000-422-41**



**Uses**

Topical Analgesic  
 Temporary relieve minor pain associated with:

- Arthritis
- Simple Backache
- Muscle Strains
- Bursitis
- Tendonitis
- Strains
- Bruises
- Cramps

**Warnings**

**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 the eyes and mucous membranes
- do not apply to wounds or damaged skin

**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
- 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.

**Inactive Ingredients**

Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80

**Directions**

**Directions**

**Adults and Children 12 years of age and older:**

- Peel off protective backing and apply sticky side to affected area.
- Carefully remove backing from patch
- Should be used up to 8 hours
- Should be used no more than 3 times a day
- **Children under 12 years of age:** Consult a doctor.

**Purpose**

Topical Analgesic

**Warnings**

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If swallowed, get medical help or contact a Poison Control Center right away.

**5% Menthol Pain Relief Patch (24 Pouches/Box) NDC: 52000-422-42**

140x80x210mm

C M Y K



## Uses

Topical Analgesic

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#### Purpose

Topical Analgesic

#### Warnings

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## COLD AND HOT MEDICATED

menthol patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52000-422
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.05 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JNI2J)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ALCOHOL 95%</b> (UNII: 7528N5H79B)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	

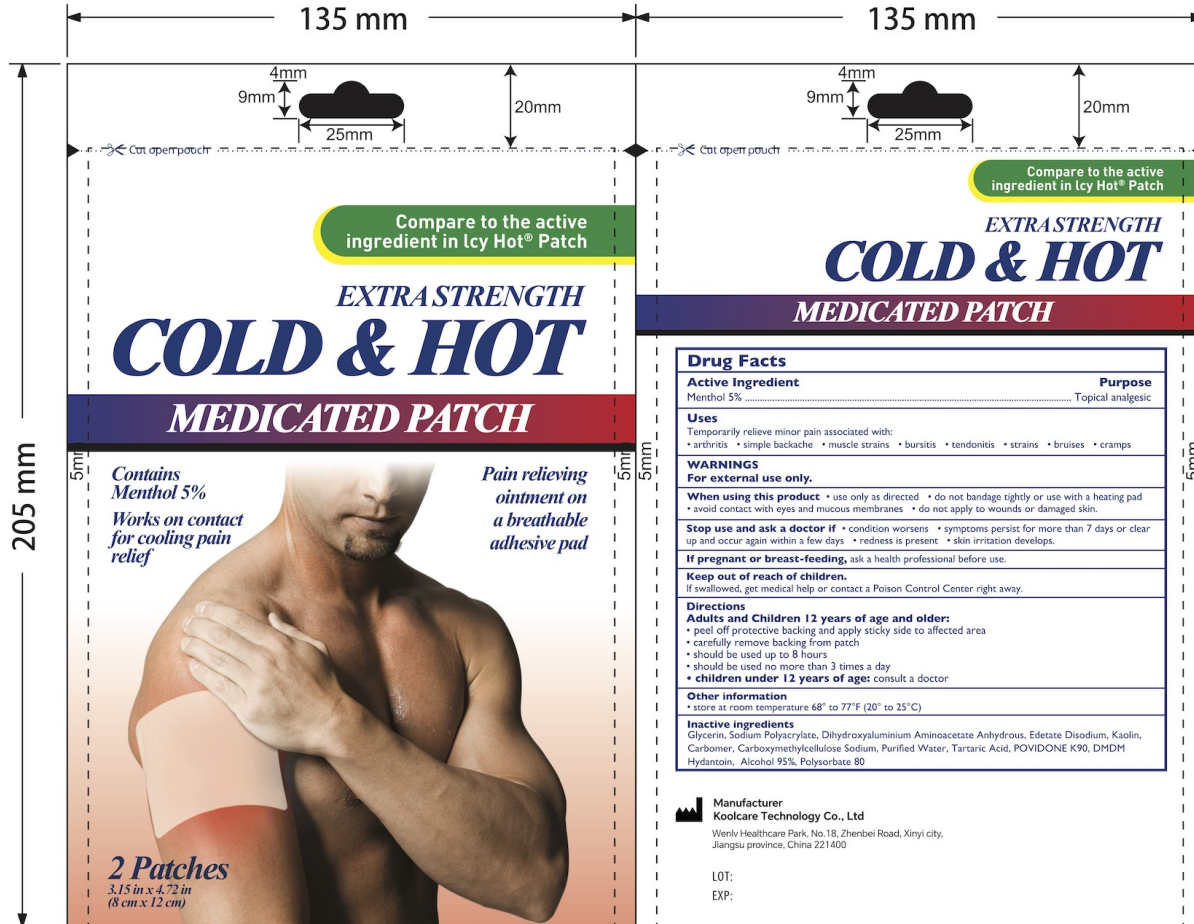
### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-422-42	24 in 1 BOX	11/25/2024	
1		2 in 1 POUCH		
1		8.5 g in 1 PATCH; Type 0: Not a Combination Product		
	NDC:52000-422			

2	NDC:52000-422-41	2 in 1 POUCH	11/25/2024
2		8.5 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 Drug	M017	11/25/2024	

**Labeler** - UNIVERSAL DISTRIBUTION CENTER, LLC (019180459)

**Registrant** - Koolcare Technology Co., Ltd (602479389)

## Establishment

Name	Address	ID/FEI	Business Operations
Koolcare Technology Co., Ltd		602479389	manufacture(52000-422)