

**COLD AND HOT MEDICATED LARGE- menthol patch**  
**Universal Distribution Center LLC**

-----  
**Cold and Hot Medicated Large Patch**

**Drug Facts**

**Active Ingredient**

Menthol 5%

**Purpose**

Topical Analgesic

**Uses**

Temporarily relieve minor aches and pains of muscles and joints due to

- simple backache • arthritis • muscle strains • bursitis • tendonitis • muscle sprains • bruises • cramps

**WARNINGS:**

**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 • 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 (1-800-222-1222) immediately.

**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 to 4 times daily

**Children under 12 years of age:** Consult a doctor.

**Other Information**

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

**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

**Compare to the active ingredient in Icy Hot® Patch**

**EXTRA STRENGTH**

**Contains Menthol 5%**

**Pain relieving ointment on a breathable adhesive pad**

**EXTRA STRENGTH COLD & HOT MEDICATED PATCH works on contact providing pain relief that lasts for hours. The thin, flexible patch is comfortable to wear and is easy to remove.**

**FAST RELIEF OF MINOR ACHES AND PAINS**

\*This product is NOT manufactured or distributed by Chattem Inc., owner of the registered trademark Icy Hot® Patch.

**Distributed by:**

Universal Distribution Center

96 Distribution Boulevard • Edison, NJ 08817

Made in P.R.C.

**Packaging**





**KEEP OUT OF REACH OF CHILDREN.**  
If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

**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 to 4 times daily

**Children under 12 years of age:** Consult a doctor.

**Other Information**  
• store at room temperature 68° to 77°F (20° to 25°C)

**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

\*This product is NOT manufactured or distributed by Chatten, Inc., owner of the registered trademark Icy Hot® Patch.



LOT:  
EXP:

ITEM#82635



6 76979 82635 6

Made in P.R.C.

Distributed By:  
Universal Distribution Center  
96 Distribution Boulevard • Edison, NJ 08817

## DRUG FACTS LABEL

<b>Drug Facts</b>	
<b>Active Ingredient</b> Menthol 5% .....	<b>Purpose</b> Topical Analgesic
<b>Uses</b> Temporarily relieve minor aches and pains of muscles and joints due to • simple backache • arthritis • muscle strains • bursitis • tendonitis • muscle sprains • bruises • cramps	
<b>WARNINGS: EXTERNAL USE ONLY</b>	
<b>When using this product</b> • 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.	
<b>STOP USE and ask a doctor if</b> • 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	
<b>If pregnant or breast-feeding,</b> ask a health professional before use.	
<b>KEEP OUT OF REACH OF CHILDREN.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.	
<b>DIRECTIONS</b> <b>Adults and Children 12 years of age and older:</b> <ul style="list-style-type: none"> <li>• Peel off protective backing and apply sticky side to affected area. Carefully remove backing from patch</li> <li>• Should be used up to 8 hours</li> <li>• Should be used no more than 3 to 4 times daily</li> </ul> <b>Children under 12 years of age:</b> Consult a doctor.	
<b>Other Information</b> • store at room temperature 68° to 77°F (20° to 25°C)	
<b>Inactive Ingredients</b> Glycerin, Sodium Polyacrylate, Dihydroxyaluminium Aminoacetate Anhydrous, Edetate Disodium, Kaolin, Carbomer, Carboxymethylcellulose Sodium, Purified Water, Tartaric Acid, POVIDONE K90, DMDM Hydantoin, Alcohol 95%, Polysorbate 80	

## COLD AND HOT MEDICATED LARGE

menthol patch

<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52000-033
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	428.5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JNI2J)	
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>ALCOHOL 95%</b> (UNII: 7528N5H79B)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-033-41	1 in 1 BOX	06/21/2017	
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 Drug	M017	06/21/2017	

**Labeler** - Universal Distribution Center LLC (019180459)**Registrant** - Universal Distribution Center LLC (019180459)**Establishment**

Name	Address	ID/FEI	Business Operations
Koolcare Technology Co., Ltd.		602479389	manufacture(52000-033)