COLD AND HOT MEDICATED PATCH- menthol patch
Universal Distribution Center LLC

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.

Cold and Hot Medicated Patch

Drug Facts

Active Ingredient

Menthol 5%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain associated with:

• arthritis • simple backache • muscle strains • bursitis • tendonitis • 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 • 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.

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

Other information

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

Inactive ingredients

glycerin, sodium polyacrylate, aluminum glycinate, kaolin, methylparaben, propylparaben, alcohol, titanium dioxide, tartaric acid, sorbitan monooleate, polysorbate 80, purified water

Compare to the active ingredient in Icy Hot® Patch

EXTRA STRENGTH

Contains Menthol 5%

Works on contact for cooling pain relief

Pain relieving ointment on a breathable adhesive pad

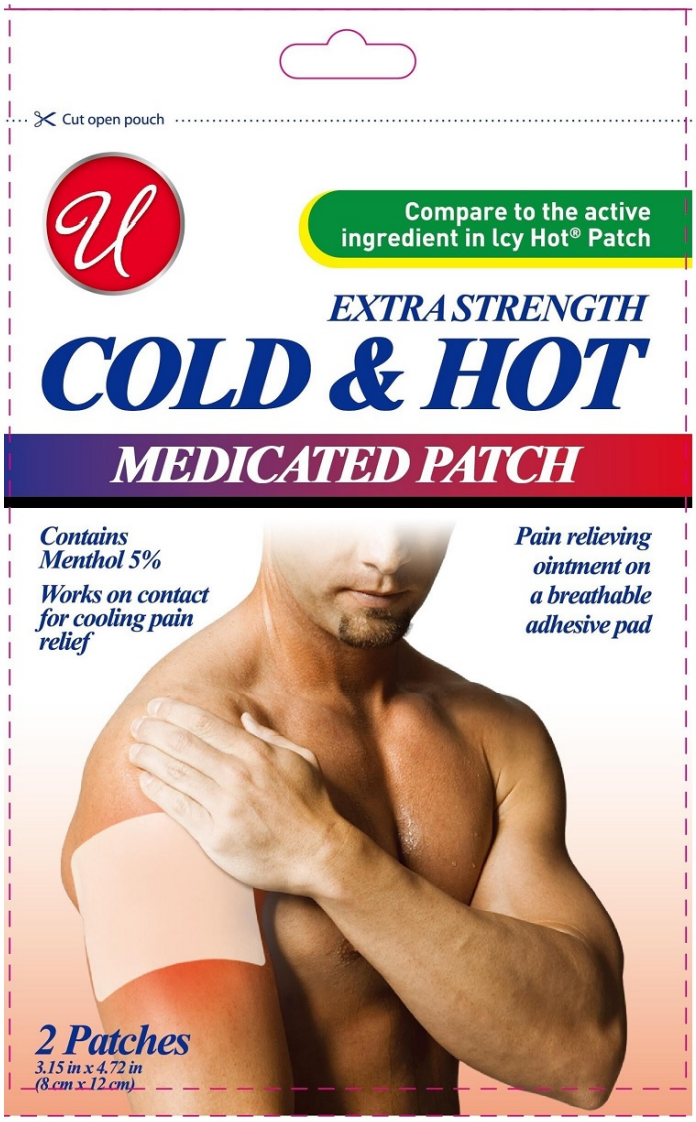
*This product is not manufactured or distributed by Chattem Inc., owner of the registered trademark Icy Hot® Patch.

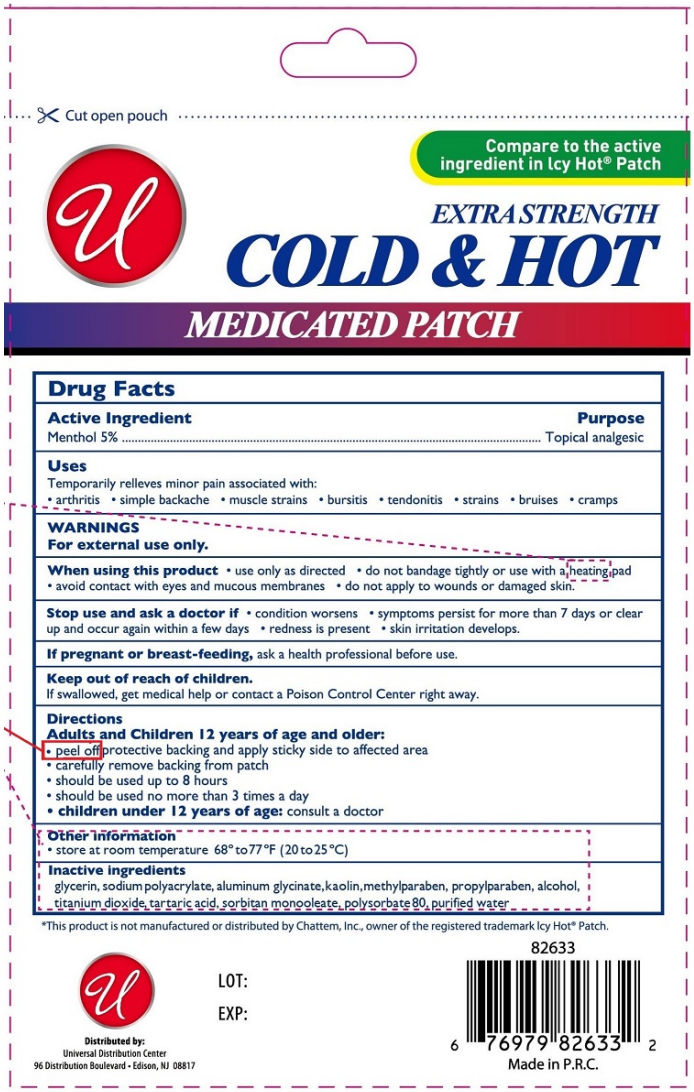
Distributed by:

Universal Distribution Center

96 Distribution Boulevard • Edison, NJ 08817

Packaging





COLD AND HOT MEDICATED PATCH

menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	205.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	

KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALCOHOL (UNII: 3K9958V90M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-032-42	1 in 1 BOX	06/21/2017	
1		2 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 not final	part348	06/21/2017	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Universal Distribution Center LLC (019180459)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dingtai Pharmaceutical Co., Ltd		420598724	manufacture(52000-032)

Revised: 3/2020 Universal Distribution Center LLC