

COLD AND HOT MEDICATED LARGE- 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 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, aluminum glycinate, kaolin, methylparaben, propylparaben, alcohol, titanium dioxide, tartaric acid, sorbitan monooleate, polysorbate 80, purified water

FAST RELIEF OF MINOR ACHES AND PAINS

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

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.

*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

✂ Cut open pouch



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

EXTRA STRENGTH COLD & HOT MEDICATED PATCH

Contains Menthol 5%

Pain relieving ointment on a breathable adhesive pad

1 Large Patch
3.94 in x 7.87 in (10 cm x 20 cm)



✂ Cut open pouch



EXTRA STRENGTH COLD & HOT MEDICATED PATCH

FAST RELIEF OF MINOR ACHES AND PAINS

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LOT:
EXP:

ITEM#82635



6 76979 82635 6
Made in P.R.C.

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

COLD AND HOT MEDICATED LARGE

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-033
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	428.5 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
DIHYDROXYALUMINUM AMINO ACETATE ANHYDROUS (UNII: 1K713C615K)	

KAOLIN (UNII: 24H4NWX5CO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
ALCOHOL (UNII: 3K9958V90M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TARTARIC ACID (UNII: W4888I119H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0K00R)	

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 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(52000-033)