

ICY HOT KIDS PAIN RELIEF- menthol patch
Chattem, Inc.

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.

Icy Hot Kids Pain Relief Patch

ICY HOT KIDS PAIN RELIEF PATCH

Drug Facts

Active ingredient

Purpose

Menthol
5%.....Topical
analgesic

Uses

temporarily relieves minor aches and pains of muscles and joints associated with: ■
arthritis ■ simple backache ■ strains ■ sprains ■ bruises

Warnings

For external use only

Do not use

- on wounds or on irritated or damaged skin
- with a heating pad

When using this product

- use only as directed
- do not bandage tightly
- avoid contact with eyes and mucous membranes
- do not expose the area to local heat or to direct sunlight
- rare cases of serious burns have been reported with products of this type
- a transient burning sensation may occur upon application but generally disappears in several days
- avoid applying into skin folds

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- redness is present or excessive skin irritation occurs
- your child experiences severe burning pain, swelling, or blistering where the product was applied

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

- children 5 years of age and older:
 - patch may be cut into smaller sizes with scissors prior to removal of the backing
 - remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
 - carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
 - once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
 - apply to affected area not more than 3 to 4 times daily
 - wash hands after applying or removing patch. Throw away the patch by folding sticky ends together.
- children under 5 years of age: ask a doctor

Inactive ingredients

aluminum hydroxide, cellulose gum, glycerin, isopropyl myristate, methyl acrylate/2-ethylhexyl acrylate copolymer, nonoxynol-30, polyacrylic acid, polysorbate 80, sodium polyacrylate, sorbitan sesquioleate, starch/acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, water

PRODUCT SHOULD BE APPLIED UNDER ADULT SUPERVISION

Keep carton as it contains important information.

PRINCIPAL DISPLAY PANEL

ICY HOT

KIDS

PAIN RELIEF PATCH

CONTAINS 5 PATCHES



ICY HOT KIDS PAIN RELIEF

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C00X)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	
METHYL ACRYLATE (UNII: WC487PR91H)	
ETHYLHEXYL ACETATE (UNII: 2C7K80A8SB)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	

SODIUM POLYACRYLATE (250000 MW) (UNII: 05I15JN12J)

ACRYLIC ACID (UNII: J94PBK7X8S)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0099-0	5 in 1 CARTON; Type 0: Not a Combination Product	01/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2023	

Labeler - Chattem, Inc. (003336013)

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Chattem, Inc.