

**ICY HOT ADVANCED RELIEF- menthol topical analgesic 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 Advanced Relief

Active Ingredient

Menthol 7.5%

Purpose

Topical analgesic

Uses

Temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- 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, broken or irritated skin
- do not use at the same time as other topical analgesics

Stop use and ask a doctor if

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

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 over 12 years :

- gently fold the patch in half to remove center section of film backing. Apply the exposed adhesive portion to the site of pain.
- remove remaining film backing from both sides and finish applying to skin
- use 1 patch for up to 12 hours, once a day

Children 12 years and younger: ask a doctor

Inactive ingredients

glyceryl hydrogenated rosinat, hydrated silica, mineral oil, PEG-400, polyisobutene, styrne/isoprene copolymer

Principal Display Panel

ICY HOT®
ADVANCED RELIEF
PAIN RELIEF PATCH
ADVANCED RELIEF at the POINT of PAIN
50% MORE MEDICINE
LONG LASTING RELIEF
FLEXIBLE, NO MESS FABRIC
Easy to Apply and Remove
Contains 4 Patches in 1 Resalable Pouch
3 15/16" x 5 1/2" (10 cm x 14 cm) each



ICY HOT ADVANCED RELIEF

menthol topical analgesic patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0805
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	210 mg

Inactive Ingredients

Ingredient Name	Strength
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0805-0	1 in 1 CARTON		
1		4 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	12/01/2012	

Labeler - Chattem, Inc. (003336013)

Revised: 11/2012

Chattem, Inc.