

**ICY HOT ADVANCED RELIEF- camphor and menthol cream
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 Cream

Drug Facts

Active ingredients

Menthol 16%

Camphor 11%

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, or medicated patch
- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- a transient burning sensation may occur upon application but generally disappears within a few days

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 :

- apply a thin layer to affected area
- message into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 3 to 4 times daily, allowing a minimum of 2-3 hours between applications
- **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**

Children 12 years and younger: ask a doctor

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, allantoin, aloe barbadensis leaf juice, cetyl alcohol, diisopropyl adipate, disodium EDTA, ethoxydiglycol, fragrance, glycerin, glyceryl stearate, menthyl lactate, methylparaben, PEG-150 stearate, pentylene glycol, 4-t-butylcyclohexanol, phenoxyethanol, polysorbate 80, propanediol, SD alcohol (5% w/w), glycine soja (soybean) sterols, steareth-21, stearic acid, triethanolamine, water, xanthan gum (309-018)

Principal Display Panel

ICY HOT[®]
ADVANCED RELIEF
PAIN RELIEF CREAM
Net WT 2 OZ (56 g)

2 MAX STRENGTH PAIN RELIEVERS
- ADVANCED RELIEF FOR TOUGH PAIN -



Relief in Minutes that Lasts for Hours!

- > ARTHRITIS > BODY ACHES > KNEE PAIN
- > JOINT PAIN > BACK PAIN > SORE MUSCLES

POWERFUL LASTING PAIN RELIEF

NEW!

ICYHOT



ADVANCED RELIEF

PAIN RELIEF CREAM

NET WT 2 OZ (56 g)

ICYHOT
ADVANCED RELIEF



Dist. by Chatham, Inc., P.O. Box 2219
Chattanooga, TN 37409-0219 USA
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ADVANCED RELIEF

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KEEP CARTON AS IT CONTAINS IMPORTANT INFORMATION
PLEASE READ AND UNDERSTAND THE ABOVE DRUG FACTS BEFORE USING

ICYHOT
ADVANCED RELIEF
PAIN RELIEF CREAM

- Begins to work on contact to bring powerful, lasting relief
- Goes on ICY to dull the pain
- Activates to HOT for a penetrating warmth to relax the pain away
- PATENT PENDING FORMULA

Close cap tightly after use.

ICY HOT ADVANCED RELIEF

camphor and menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0801
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.11 g in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.16 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MENTHYL LACTATE, (-) (UNII: 2BF9E65L7I)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PEG-150 STEARATE (UNII: 7BSG7DF10Q)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
4-TERT-BUTYLCYCLOHEXANOL (UNII: K0H1405S9C)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPANEDIOL (UNII: 5965N8W85T)	
SOY STEROL (UNII: PL360EPO9J)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0801-0	1 in 1 CARTON		
1		56 g in 1 TUBE		

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)

Establishment

Name	Address	ID/FEI	Business Operations
Chattem Plant 2		830410721	ANALYSIS(41167-0801) , LABEL(41167-0801) , MANUFACTURE(41167-0801) , PACK(41167-0801) , RECOVERY(41167-0801) , RELABEL(41167-0801) , REPACK(41167-0801)

Revised: 3/2013

Chattem, Inc.