

ICY HOT VANISHING SCENT- menthol gel 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 Vanishing Scent

Drug Facts

Active ingredient

Menthol 2.5%

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. Read and follow all directions and warnings on this carton.
- avoid contact with eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
- 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
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding,

ask a health care 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
- squeeze desired amount of Icy Hot[®] pain relieving gel onto affected area
- using the sponge-top applicator, massage dispensed gel into painful area until thoroughly absorbed
- repeat as necessary, but not more than 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

alcohol denat. (15%), allantoin, aloe barbadensis leaf juice, carbomer, DMDM hydantoin, glycerin, methylparaben, phenoxyethanol, propylparaben, steareth-2, steareth-21, triethanolamine, water

Keep carton as it contains important information.

Close cap tightly after use.

PRINCIPAL DISPLAY PANEL

MENTHOL 2.5%

NEW LOOK

ICYHOT[®]

ORIGINAL

VANISHING SCENT

PAIN RELIEVING GEL

Net wt 2.5 oz (70.8 g)

MENTHOL 2.5%

NEW LOOK

ICYHOT ORIGINAL

VANISHING SCENT PAIN RELIEF GEL

FEEL IT WORKING INSTANTLY

No Mess Sponge Applicator

▶ Pain Relief for Muscles and Joints

▶ Icy to Dull, Hot to Relax

▶ Scent Disappears in Minutes

ICYHOT ORIGINAL

NET WT 2.5 OZ (70.8 g)

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 ■ sprains ■ bruises ■ cramps

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 ■ avoid applying into skin folds

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
 ■ you experience signs of skin injury, such as 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
adults and children over 12 years:
 ■ apply generously to affected area
 ■ squeeze desired amount of Icy Hot® pain relieving gel onto affected area
 ■ using the sponge-top applicator, massage dispensed gel into painful area until thoroughly absorbed
 ■ repeat as necessary, but no more than 4 times daily
children 12 years or younger: ask a doctor

Inactive ingredients
 alcohol denat. (15%), allantoin, aloe barbadensis leaf juice, carbomer, DMDM hydantoin, glycerin, methylparaben, phenoxethanol, propylparaben, steareth-2, steareth-21, triethanolamine, water

PLEASE READ AND UNDERSTAND THE DRUG FACTS BEFORE USING
 Close cap tightly after use.

MENTHOL 2.5%

ICYHOT ORIGINAL

VANISHING SCENT PAIN RELIEF GEL

FEEL IT WORKING INSTANTLY

▶ Simple Backache

▶ Muscle Strains

▶ Sprains

▶ Bruises

ICYHOT ORIGINAL

NET WT 2.5 OZ (70.8 g)

NEW LOOK

Dist. by Chatterm, Inc., a Sanofi Company
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 Chattanooga, TN 37409-0219 USA
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0 41167 00923 9

ICY HOT VANISHING SCENT

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0092
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.025 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0092-0	1 in 1 CARTON	03/01/2007	
1		71 g in 1 TUBE; 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	03/01/2007	

Labeler - Chattem, Inc. (003336013)

Establishment

Name	Address	ID/FEI	Business Operations
CHATTEM, INC.		830410721	manufacture(41167-0092)

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CHATTEM, INC.		003336013	manufacture(41167-0092)

Revised: 11/2021

Chattem, Inc.