

ICY HOT PAIN RELIEVING CREAM- menthol and methyl salicylate cream
A-S Medication Solutions

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

ICYHOT® PAIN RELIEVING STICK
Drug Facts

Active ingredient

Menthol 10%

Methyl salicylate 30%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis
- simple backache
- muscle strains
- sprains
- bruises
- cramps

Warnings

For external use only

SEE INSIDE LABEL FOR COMPLETE DRUG FACTS

Allergy Alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

When using this product

- use only as directed
- do not bandage tightly or use with a heating pad
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin

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 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 generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

children 12 years or younger: ask a doctor

Inactive ingredients

ceresin, cyclomethicone, hydrogenated castor oil, microcrystalline wax, paraffin, PEG-150 distearate, propylene glycol, stearic acid, stearyl alcohol (245-111)

ICYHOT® PAIN RELIEVING BALM

Drug Facts

Active ingredient

Menthol 7.6%

Methyl salicylate 29%

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Topical analgesic

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ask a health care professional before use.

Keep out of reach of children.

If case of accidental ingestion, get medical help or contact a Poison Control Center right away.

continued on cap

Directions

adults and children over 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
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Inactive ingredients

paraffin, white petrolatum (245-109)

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Inactive ingredients

carbomer, cetyl esters, emulsifying wax, oleth-3 phosphate, stearic acid, triethanolamine, water (245-110)

Close cap tightly after use.

HOW SUPPLIED

Product: 50090-4357

NDC: 50090-4357-0 35.4 g in a TUBE / 1 in a CARTON

Menthol and Methyl Salicylate



ICY HOT PAIN RELIEVING CREAM

menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4357(NDC:41167-0088)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4357-0	1 in 1 CARTON	06/14/2019	
1		35.4 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	06/01/1991	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4357)

Revised: 6/2019

A-S Medication Solutions