

SIGNATURE CARE COOL HEAT- menthol, methyl salicylate cream

Safeway

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.

Better Living Brands LLC Cool Heat Cream Drug Facts

Active ingredients

Menthol 10%

Methyl salicylate 30%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with

- arthritis
- simple backache
- strains
- sprains
- bruises

Warnings

For external use only

When using this product

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

Stop use and ask a doctor if

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

adults and children over 12 years

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, not more than 3 to 4 times daily

children 12 years or younger ask a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

carbomer homopolymer, cetyl esters wax, emulsifying wax, oleth-3 phosphate, purified water, stearic acid, trolamine

Questions or comments?

1-888-723-3929

Principal Display Panel

Extra Strength

Cool Heat Cream

COLD & HOT Therapy For Pain

COMPARE TO Icy Hot[®] Cream active ingredients

Temporary relief of:

Arthritis, back aches, body aches & sore muscles

Extra Strength

Cool Heat Cream

MENTHOL 10%, METHYL SALICYLATE 30%

Pain Relieving Cream

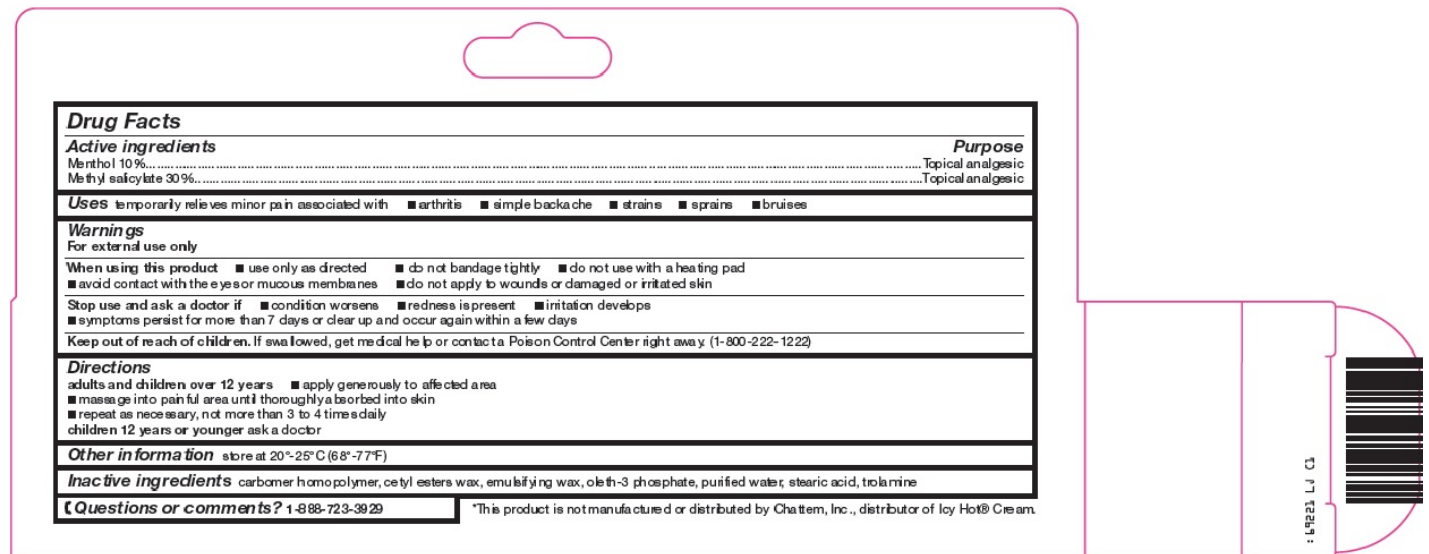
COLD & HOT Therapy For Pain

COMPARE TO Icy Hot[®] Cream active ingredients

Temporary relief of:

Arthritis, back aches, body aches & sore muscles

NET WT 3 OZ (85 g)



SIGNATURE CARE COOL HEAT

menthol, methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-339
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	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)	
WATER (UNII: 059QF0K00R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-339-85	1 in 1 CARTON	12/02/2015	
1		35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21130-339-21	1 in 1 CARTON	12/03/2015	
2		85 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	12/02/2015	

Labeler - Safeway (009137209)

Revised: 12/2019

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