

COOL HEAT- menthol and methyl salicylate cream
Dolgenercorp 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.

Cool Heat

Active ingredients

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

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

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If pregnant or breast-feeding, 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.

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

carbomer, cetyl esters, emulsifying wax, oleth-3 phosphate, stearic acid, triethanolamine, water.

PRINCIPAL DISPLAY PANEL

EXTRA STRENGTH

COOL HEAT PAIN RELIEVING CREAM

NET WT 1.25 OZ (35 g)

DG™ | health

Compare to the active ingredients of Icy Hot®*

Extra Strength Cool Heat

Pain Relieving Cream
Menthol 10%
Methyl Salicylate 30%

- Goes on cool to dull pain
- Activates to heat for a penetrating warmth

Extra Strength Cool Heat

Pain Relieving Cream

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Extra Strength Cool Heat

Pain Relieving Cream

NET WT 1.25 OZ (35 g)

Extra Strength
Cool Heat
Pain Relieving Cream

100% Satisfaction Guaranteed!
(888) 309-9030

DISTRIBUTED BY DOLGENCORP, LLC
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

MADE IN INDIA



A0627

*This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark Icy Hot®.

Drug Facts
Active ingredients
Menthol 10% Topical analgesic
Methyl salicylate 30% Topical analgesic
Uses temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises ■ cramps
Warnings
For external use only
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 or symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ irritation develops.
If pregnant or breast-feeding ask a health professional before use.
Keep out of reach of children. In case of accidental ingestion, 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
Children 12 years or younger: ask a doctor
Inactive ingredients carbomer, cetyl esters, emulsifying wax, oleth 3 phosphate, stearic acid, triethanolamine, water.

Lot no.:
PRD :
EXP :

COOL HEAT
menthol and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-405
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
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-405-35	35 g in 1 TUBE; Type 0: Not a Combination Product	06/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/29/2016	

Labeler - Dolgencorp Inc (068331990)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(55910-405)