COLD AND HEAT PAIN RELIEVING CREAM- menthol and methyl salicylate cream
Velocity Pharma LLC

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.

Cold and Heat Pain Relieving Cream

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:

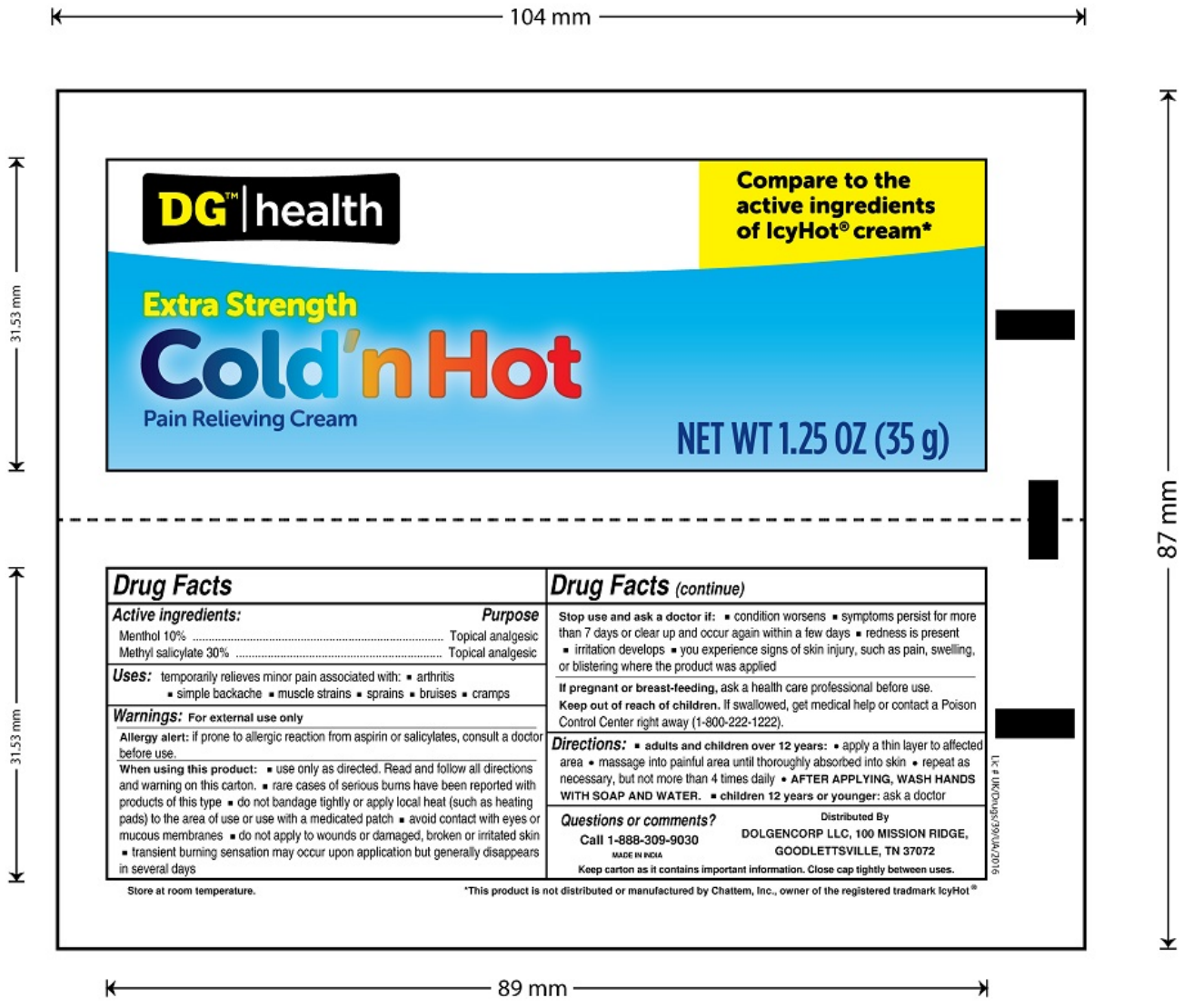
- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 4 times daily

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)

PRINCIPAL DISPLAY PANEL



COLD AND HEAT PAIN RELIEVING CREAM

menthol and methyl salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76168-402
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:76168-402-44	1 in 1 CARTON	08/09/2018	
1		35 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	08/09/2018	

Labeler - Velocity Pharma LLC (962198409)

Revised: 8/2018 Velocity Pharma LLC