MEIJER COLD AND HOT THERAPY- menthol, methyl salicylate cream Meijer, 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.

Meijer Cold & Hot Therapy Pain Relieving Cream 1.25oz 25349 ZDP Active Ingredients Purpose

Menthol 10%......Topical Analgesic

Methyl Salicylate 30%......Topical Analgesic

Uses

temporarily relieves minor pain associated with:

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

Warnings

For external use only

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

Do not use

- on wounds or damaged skin
- with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs
- redness of the skin is present

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 (1-800-222-1222) right away.

Directions

use only as directed

adults and children 12 years of age and older:

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

childen under 12 years of age: ask a doctor

Other Information

• store at room temperature 20-25°C (68-77°F)

Inactive ingredients carbomer, cetostearyl alcohol, cetyl esters wax, polysorbate 60, purified water, steareth-20, stearic acid, trolamine



MEIJER COLD AND HOT THERAPY

menthol, methyl salicylate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-858

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			
TROLAMINE (UNII: 903K93S3TK)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
WATER (UNII: 059QF0KO0R)				
STEARETH-20 (UNII: LOQ8IK9E08)				
POLYSORBATE 60 (UNII: CAL22UVI4M)				
CETYL ESTERS WAX (UNII: D072FFP9GU)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41250-858- 35	1 in 1 CARTON	07/02/2020			
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	07/02/2020		

Labeler - Meijer, Inc. (006959555)

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