

MEIJER EXTRA STRENGTH COLD AND HOT THERAPY PAIN RELIEVING TOPICAL ANALGESIC- menthol, unspecified form and methyl salicylate cream
Meijer Distribution, 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® Extra Strength Cold & Hot Therapy Pain Relieving Cream
Topical Analgesic

Drug Facts

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

Warnings

For external use only

Test on a small patch before applying generously.

Allergy alert

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

When using this product

- use only as directed. Read and follow all directions and warnings on this label
- do not bandage tightly or apply local heat (such as heating pads) to the area of use or use with a medicated patch
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- a transient burning sensation may occur upon application but generally disappears in seven days

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

- irritation develops
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breastfeeding, 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

Adults and children over 12 years:

- apply to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily
- **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER.**

Children 12 years or younger: ask a doctor

Other information

Keep tightly closed. Store at room temperature.

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, carbomer, cetareth-20, cetaryl alcohol, oleth-3 phosphate, phenoxyethanol, polysorbate 60, sodium hydroxide, stearic acid, water.

Questions or comments?

1-866-567-8600

**DIST. BY MEIJER
DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544**

PRINCIPAL DISPLAY PANEL - 35.4 g Tube Carton

Compare to
Icy Hot[®] Active
Ingredients*

meijer[®]

EXTRA STRENGTH
cold & hot therapy

Menthol 10% (Topical Anesthetic)

Methyl Salicylate 30% (Topical Anesthetic)

Pain Relieving Cream

Body & Backache | Bruises | Arthritis | Sore Muscles

NET WT 1.25 OZ (35.4 g)



MEIJER EXTRA STRENGTH COLD AND HOT THERAPY PAIN RELIEVING TOPICAL ANALGESIC

menthol, unspecified form and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-378
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	100 mg in 1 g
Methyl Salicylate (UNII: LAV5U5022Y) (Salicylic Acid - UNII:O414PZ4LPZ)	Methyl Salicylate	300 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
Carbomer Homopolymer, Unspecified Type (UNII: 0A5MM307FC)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWJY)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Oleth-3 Phosphate (UNII: 8Q0Z18J1VL)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-378-01	1 in 1 CARTON	11/30/2020	
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	11/30/2020	

Labeler - Meijer Distribution, INC (006959555)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
Sigan Industries INC.		255106239	MANUFACTURE(41250-378)

Revised: 1/2022

Meijer Distribution, INC