

**MEIJER COLD THERAPY PAIN RELIEF- menthol gel**  
**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.*

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**Meijer Cold Therapy Pain Relief**

***Drug Facts***

***Active Ingredients***

Menthol 4%

***Purpose***

Cooling Pain Relief

***Uses***

Temporary relief from minor aches and pains of sore muscles and joints associated with • arthritis • backache • strains • sprains

***Warnings***

**For external use only.**

**Flammable:** Keep away from excessive heat or open flame

**Ask a doctor before use if you have:**

Sensitive skin

**When using this product:**

• Avoid contact with the eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin or if excessive irritation develops • Do not bandage • Wash hands after use with cool water

**Do not use**

• with heating pad or device • Store in cool dry place.

**Stop use and ask a doctor if:**

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur.

**If pregnant or breast-feeding:**

Ask a health professional before use

**Keep out of reach of children:**

If accidentally ingested, get medical help or contact a Poison Control Center immediately.

***Directions***

- **Adults and Children 2 years of age and older:** rub a thin film over affected areas not more than four times daily; massage not necessary.
- **Children under 2 years of age:** Consult physician

***Inactive Ingredients***

Aloe Barbadensis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

**Package Labeling:**

**meijer**

NDC XXXXX-XXX-XX

Compare to  
Biofreeze®  
active ingredient\*

**COLD THERAPY**  
**pain relief**  
**gel**

TOPICAL ANALGESIC

**Soothing Menthol 4%**  
**Paraben Free**

**For Arthritis, Sore Muscles,**  
**Back Pain and Joints**

**Vanishing Scent**

**3 FL OZ (89 mL)**

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\*This product is not distributed by Hygenic Intangible Property Holding Co. owner of the registered trademark Biofreeze®

DIST. BY MEIJER DISTRIBUTION, INC.  
GRAND RAPIDS, MI 49544  
www.meijer.com



Does not contain  
NSAIDs, Ibuprofen,  
Aspirin, or Salicylate

P10557 14703 REV 0

PD 4331516



**MEIJER COLD THERAPY PAIN RELIEF**

menthol gel

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:41250-864

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARCTIUM LAPPА ROOT</b> (UNII: 597E9BI3Z3)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>GREEN TEА LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ILEX PARAGUARIENSIS LEAF</b> (UNII: 1Q953B4O4F)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>MELISSA OFFICINALIS LEAF</b> (UNII: 50D2ZE9219)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-864-25	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/22/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/22/2018	12/31/2025

**Labeler** - Meijer Distribution, Inc. (006959555)

### Establishment

Name	Address	ID/FEI	Business Operations
Span Packaging Services LLC		117101131	manufacture(41250-864)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Essence, LLC		825646862	manufacture(41250-864)

