GEL COOLING PAIN RELIEF- menthol gel Meijer Distribution

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.

Gel Cooling Pain Relief 894.001/894AA rev 1

Active ingredient

Menthol 4%

Purpose

External analgesic

Use

for temporary relief from minor aches and pains of muscles & joints associated with

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only

Flammable, keep away from fire or flame.

When using this product

- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information

store in a cool dry place with lid closed tightly

Inactive ingredients

Aloe barbadensis leaf juice, Arctium lappa root extract, Arnica montana flower extract, blue 1, Boswellia carterii resin extract, Calendula officinalis flower extract, Camellia sinensis leaf extract, camphor, carbomer, Chamomilla recutita (matricaria) flower extract, glycerin, Ilex paraguariensis leaf extract, isopropyl alcohol, isopropyl myristate, Juniperus communis fruit extract, Melissa officinalis extract, silica, tocopheryl acetate, triethanolamine, water, yellow 5

*This product is not manufactured or distributed by Biofreeze Performance Health, distributor of BioFreeze® Gel Fast Acting Menthol Pain Relief.

Questions? 1-888-593-0593 DISTRIBUTED BY MEIJER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544 www.meijer.com

www.meijer.com/satisfaction

principal display panel

Compare to BioFreeze Gel Menthol Pain Relief*

Meijer

Cooling Therapy

Pain Relief Gel

Topical Analgesic

Soothing Menthol

For arthritis, back pain, sore muscles and joints

Paraben-free

3 FL OZ (89 mL)



GEL COOLING PAIN RELIEF

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79481-0894
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FRANKINCENSE (UNII: R9XLF1R1WM)	
CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CHAMOMILE (UNII: FGL3685T2X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
JUNIPER BERRY (UNII: O84B5194RL)	
MELISSA OFFICINALIS LEAF OIL (UNII: PTP6R7263M)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging			
# Item Co	de Package Description	Marketing Start Date	Marketing End Date
NDC:79483	74 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	08/16/2022	
NDC:79483 0894-2	89 mL in 1 TUBE; Type 0: Not a Combination Product	08/16/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/15/2020	
final	par 10	02/13/2020	

Labeler - Meijer Distribution (006959555)

Registrant - Vi Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(79481-0894)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(79481-0894)

Revised: 9/2022 Meijer Distribution