

## **GEL COOLING PAIN RELIEF- menthol gel**

### **Topco**

*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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**Top Care 894 894.001/894AA 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

**Questions or comments**

1-888-423-0139

**Adverse Reactions Section**

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

TOPCO VIJA 0321

QUESTIONS? 1-888-423-0139

topcare@topco.com

QUALITY GUARANTEED

This products is not manufactured or distributed by Biofreeze Performance Health, distributor of BioFreeze Gel Cold Therapy Pain Relief.

**principal display panel**

TopCare

health

COMPARE TO BIOFREEZE GEL FAST ACTING MENTHOL PAIN RELIEF

Cooling Therapy Pain Relief

Pain

Relieving

Gel

with Menthol 4%

- For Arthritis, Back Pain, Sore Muscles & Joints
- Disappearing Scent
- Fast Acting Menthol Pain Relief
- Paraben-Free

3 FL OZ (89 mL)

NDC 00000-000-00



COMPARE TO BIOFREEZE® GEL FAST ACTING MENTHOL PAIN RELIEF\*

**Cooling Therapy  
Pain Relief**

**Pain  
Relieving  
Gel**

**with Menthol 4%**

- **For Arthritis, Back Pain,  
Sore Muscles & Joints**
- **Disappearing Scent**
- **Fast Acting Menthol  
Pain Relief**



GEL COOLING PAIN RELIEF			
menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-894
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	160 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: P0M7O4Y7YD)			
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 WHOLE (UNII: YF70189L0N)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 9O3K93S3TK)			

**water** (UNII: 059QF0KO0R)

**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-894-21	89 mL in 1 TUBE; Type 0: Not a Combination Product	06/24/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/24/2021	

**Labeler** - Topco (006935977)

**Registrant** - Vi Jon, LLC (790752542)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(76162-894)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(76162-894)

Revised: 8/2022

Topco