

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

*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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### **Drug Facts 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

**Adverse Reactions Section**

Biofreeze is a registered trademark of Biofreeze Performance Health, Cuyahoga Falls, OH Biofreeze Performance Health is not affiliated with The Kroger Co. or this product.

DISTRIBUTED BY

THE KROGER CO.

CINCINNATI, OHIO 415202

QUALITY GUARANTEE

800-632-6900

[www.kroger.com](http://www.kroger.com)

**principal display panel**

COMPARE TO the active ingredient in BIOFREEZE PAIN RELIEF GEL

Kroger

Cooling

Therapy

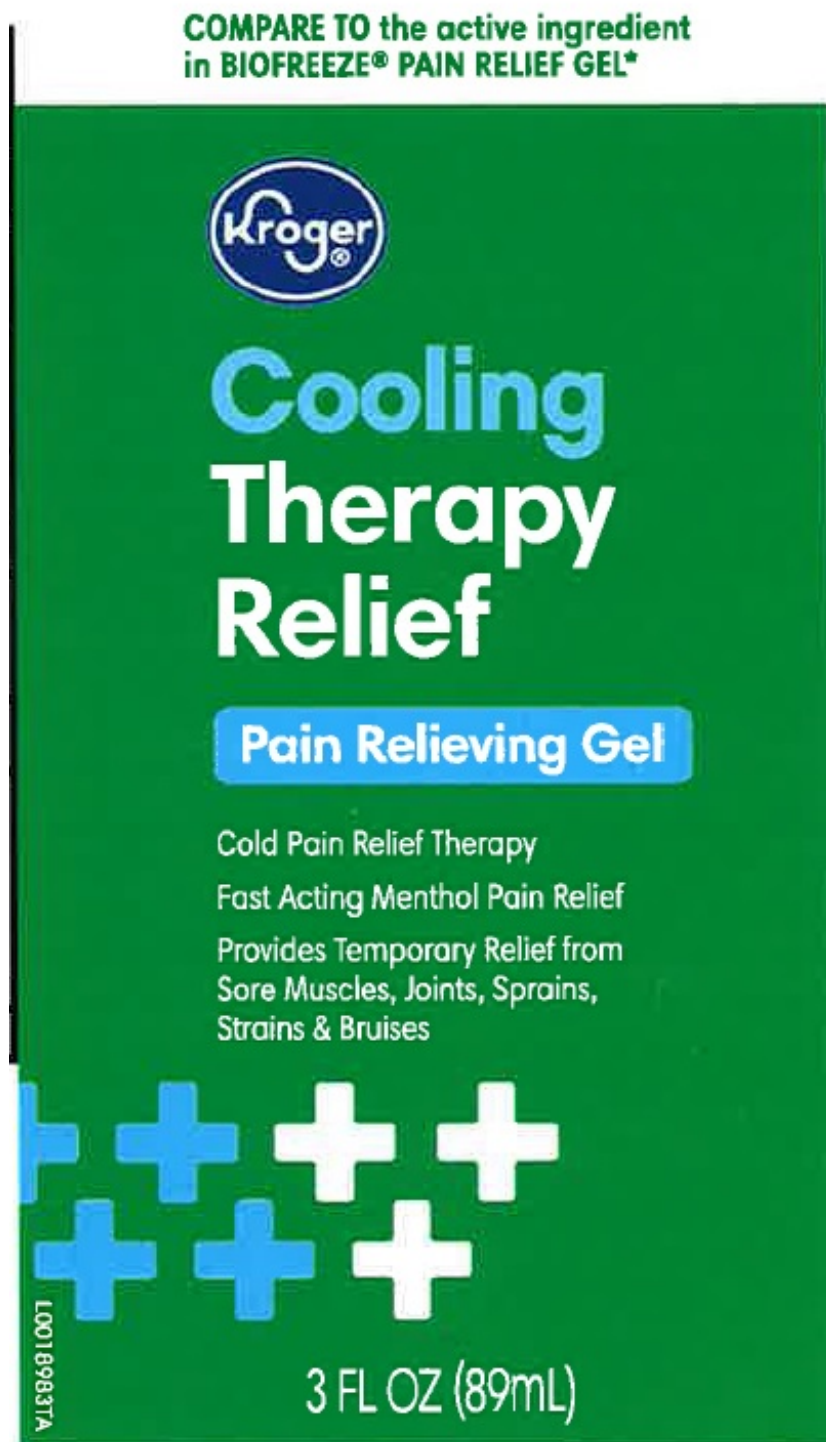
Relief

Pain Relieving Gel

Cold Pain Relief Therapy

Fast Acting Menthol Pain Relief

Provides Temporary Relief from  
Sore Muscles, Joints, Sprains,  
Strains & Bruises  
3 FL OZ (89 mL)



## GEL COOLING PAIN RELIEF

menthol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-043
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	160 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ARCTIUM LAPPA ROOT</b> (UNII: 597E9BI3Z3)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FRANKINCENSE</b> (UNII: R9XLF1R1WM)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<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>JUNIPER BERRY</b> (UNII: O84B5194RL)	
<b>MELISSA OFFICINALIS WHOLE</b> (UNII: YF70189L0N)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-043-21	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2020	
2	NDC:30142-043-18	74 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	02/15/2020	

### Marketing Information

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

**Labeler** - Kroger (006999528)

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Vi Jon, LLC		790752542	manufacture(30142-043)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Vi Jon, LLC		088520668	manufacture(30142-043)

Revised: 3/2022

Kroger