

## **RITE AID COOL THERAPY GEL- menthol gel**

### **Rite Aid**

*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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## **Rite Aid Cool Therapy Gel**

### **Drug Facts**

#### **Active Ingredients**

Menthol 4%

#### **Purpose**

Topical Analgesic

#### **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 a heating pad or device

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

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

##### **If pregnant or breast-feeding:**

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 2 years of age and older:** Rub a thin film over affected areas not more than 4 times daily; massage not necessary

**Children under 2 years of age:** Consult physician

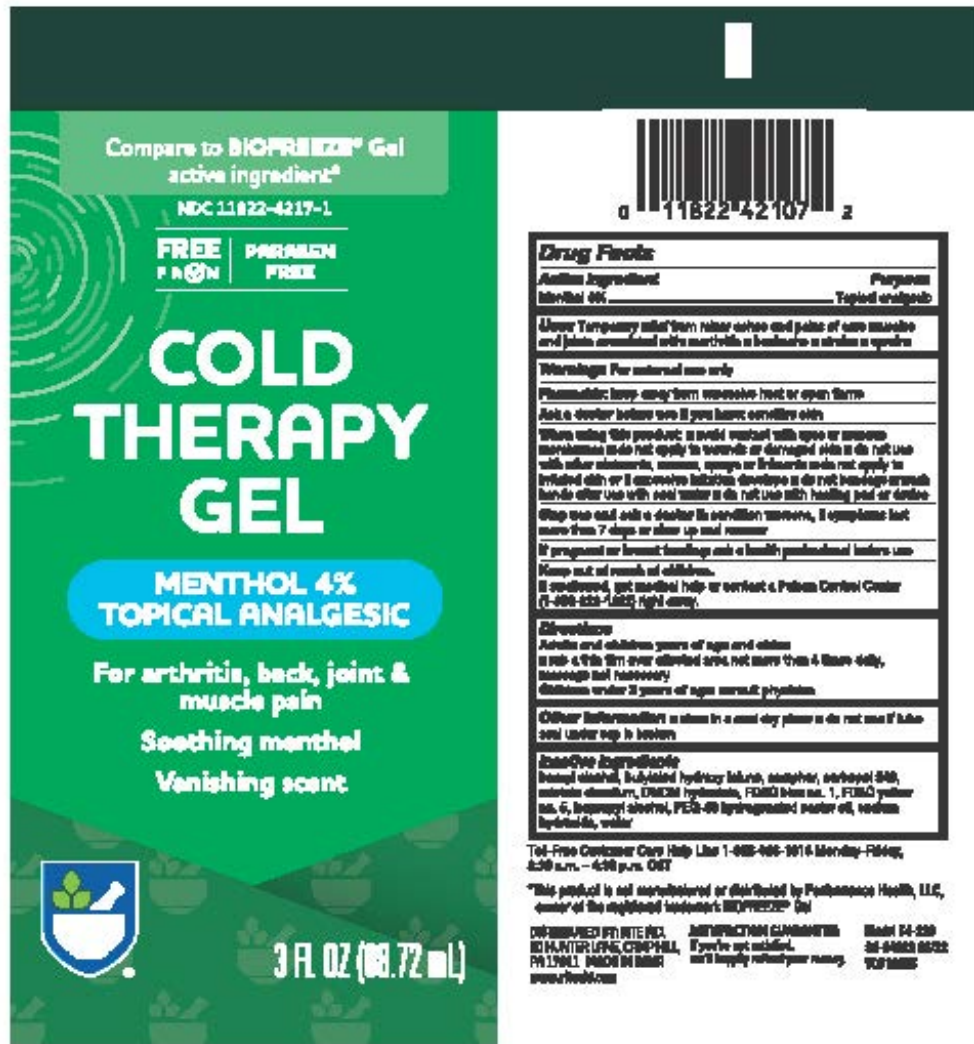
***Inactive Ingredients***

benzyl alcohol, butylated hydroxy toluene, camphor, carbopol 940, edetate disodium, DMDM hydantoin, FD&C blue No.1, FD&C Yellow No. 5, Isopropyl Alcohol, PEG-40 hydrogenated castor oil, sodium hydroxide, Water

***Questions or Comments***

1-866-326-1313 Monday- Friday 8:30am-4:30 pm CST

**Package Labeling:**



Drug Facts	
<b>Active Ingredient</b>	<b>Paraben</b>
Menthol 4%	Topical analgesic
<b>Uses</b> Temporary relief from minor aches and pains of sore muscles and joint associated with arthritis in hands or strains & sprains	
<b>Warnings</b> For external use only	
<b>Pharmacist</b> Keep away from moisture heat or open flame	
Ask a doctor before use if you have sensitive skin	
When using this product: avoid contact with eyes or mucous membranes do not apply to wounds or damaged skin do not use with other ointments, creams, soaps or lotions do not apply to irritated skin or if sensitive skin develops do not rub massage or wash hands after use with cool water do not use with heating pad or device	
Stop use and ask a doctor in condition worsens, if symptoms last more than 7 days or show up and return	
If pregnant or breast-feeding ask a health professional before use	
Keep out of reach of children.	
If swallowed, get medical help or contact a Poison Control Center (1-800-368-5888) right away.	
<b>Directions</b>	
Adults and children years of age and older	
Rub 4-6 thin strips over affected area not more than 4 times daily, massage not necessary	
Children under 2 years of age consult physician	
<b>Other Information</b> Use in a cool dry place or do not use if label seal under cap is broken	
<b>Inactive Ingredients</b>	
Benzyl alcohol, Isobutyl hydroxy toluene, menthyl crotylate, menthyl salicylate, menthyl salicylate, D,L-menthyl salicylate, FD&C Blue No. 1, FD&C Yellow No. 6, Isopropyl alcohol, PEG-90 hydrogenated castor oil, sodium hydroxide, water	

Toll-Free Customer Care Help Line 1-888-466-3814 Monday-Friday, 8:30 a.m. - 4:30 p.m. CST

\*This product is not manufactured or distributed by Performance Health, LLC, owner of the registered trademark BIOPREIZEN® (S)

DO NOT USE IF: THE SEAL IS BROKEN OR DAMAGED. IF YOU GET SWALLOWED, DO NOT INDUCE VOMITING. IF YOU GET SWALLOWED, DRINK WATER. IF YOU GET SWALLOWED, DRINK WATER. IF YOU GET SWALLOWED, DRINK WATER.

## RITE AID COOL THERAPY GEL

menthol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-4217
<b>Route of Administration</b>	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
BENZYL ALCOHOL (UNII: LKG8494WBH)	

<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-4217-1	88.72 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2022	

**Labeler - Rite Aid (014578892)**

### Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	manufacture(11822-4217)

Revised: 5/2022

Rite Aid