

COPPERGEL- camphor, menthol gel
CopperRelief, LLC

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.

CopperGel

DRUG FACTS:

ACTIVE INGREDIENTS:

Camphor 3.5%

Menthol 3.5%

Purpose:

Topical Analgesic

USES: for the temporary relief of minor aches and pains in muscles and joints associated with:

- strains
- sprains
- sports injuries
- arthritis
- bruises

WARNINGS:

For external use only.

Do not use

- with other topical pain relievers
- with heating pads or heating devices

When using this product

- do not get into eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- redness or irritation develops

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

- clean the affected area before applying product
- adults and children 2 years of age and older: apply to affected not more than 3 to 4 times daily

INACTIVE INGREDIENTS: Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Blue 1, Copper PCA, Ethylhexylglycerin, Eucalyptus Globulus (Eucalyptus) Leaf Oil, Isopropyl Alcohol, Phenoxyethanol, Triethanolamine, Water (Aqua)

Distributed By: Copper Relief, LLC

Wayzata, MN 55391

www.coppergel.com

MADE IN THE USA

CopperGel

KNOCK OUT THE PAIN™

Topical Analgesic Gel

NET WT. 3 OZ (85g)

DRUG FACTS: (continued)
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COPPERGEL

camphor, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72081-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.5 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	

CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546 YLW6E6)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
COPPER PIDOLATE (UNII: 497G7G1SL1)	
WATER (UNII: 059QF0K00R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72081-001-03	1 in 1 CARTON	02/05/2018	
1		85 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/05/2018	

Labeler - CopperRelief, LLC (080979585)

Revised: 2/2018

CopperRelief, LLC