

QUALITY CHOICE COLD THERAPY GEL- menthol gel
Chain Drug Marketing Association, Inc.

Quality Choice Cold Therapy Gel, 4oz

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 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, if symptoms last more than 7 days or clear up and reoccur

If pregnant or breastfeeding:

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 area not more than 4 times daily, massage is not necessary

children under 2 years of age: consult a physician

Other Info

- store in a cool dry place
- do not use if tube seal under cap is broken

Inactive Ingredients

Inactive ingredients

benzyl alcohol, butylated hydroxytoluene, 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

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- arthritis
- backache
- strains
- sprains

Active ingredient

Menthol 4%

Purpose

Topical analgesic



NDC 83324-0007-04



* Compare to the active ingredient in BIO FREEZE® GEL

Cold Therapy Gel

Menthol 4% / Topical Analgesic

For arthritis, back, joint & muscle pain

Soothing Menthol

Vanishing Scent

4 FL OZ (118.2ml)



Drug Facts

Active ingredient	Purpose
Menthol 4%	Topical analgesic

Uses
Temporary relief from minor aches and pains of sore muscle and joints associated with arthritis, osteoarthritis, sprains, strains, muscle spasms

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 eyes or mucous membranes and do not apply to wounds or damaged skin and do not use with other ointments, creams, sprays or liniments and do not apply to irritated skin or if excessive irritation develops do not bandage or wrap hand or use with cool water and do not use with heating pad or device

Stop use and ask a doctor if condition worsens, if symptoms last more than 7 days or clear up and recur

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 (1-800-328-1222) right away.

Directions
Adults and children 2 years of age and older: rub a thin film over affected area no more than 4 times daily, reapply not necessary
Children under 2 years of age: consult physician

Other information store in a cool dry place and do not use if tube seal under cap is broken

Inactive ingredients benzyl alcohol, butylated hydroxytoluene, camphor, carbopol 940, edetate disodium, DMCM hydroxy, FD&C blue no. 1, FD&C yellow no. 5, isopropyl alcohol, PEG-40 hydrogenated castor oil, sodium hydroxide, water

*This product is not manufactured or distributed by Performance Health, LLC, owner of the registered trademark BIO FREEZE® Gel



Distributed by QCH, Inc.
New, ME 04275
www.qualitychoice.com
Qualityline 200-675-2262

Made in India
M-044 39-2208
2-2-2019 04/25
VCM0005

QUALITY CHOICE COLD THERAPY GEL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-007
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
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	

CARBOMER 940 (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
WATER (UNII: 059QF0KO0R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-007-04	118.2 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/01/2023	

Labeler - Chain Drug Marketing Association, Inc. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Astonea Labs Private Label		878533295	manufacture(83324-007)

Revised: 3/2024

Chain Drug Marketing Association, Inc.