

HOT ICE SOOTHING ANALGESIC- camphor and menthol gel
Quality Care Distributors 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.

Ice Cold Analgesic Gel

Drug Facts

Active Ingredients

Menthol 1%

Camphor 0.5%

Purpose

Topical analgesic

Uses

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

- simple backache
- 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 use in or near eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask doctor if

- condition worsen
- symptoms last more than 7 days or clear up and occurs again with 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 swallowed, get medical help or contact a Poison Control Center right way.

Directions

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

Inactive ingredients

Benzyl alcohol, butylated hydroxy toluene, carbopol, colour brilliant blue, creasmer RH 40, disodium Edta, isopropyl alcohol, propylene glycol, purified water, sodium hydroxide

Principal Display Panel

FamilyCare

ICE

COLD

ANALGESIC GEL

NET WT. 8 OZ. (227 g)

6 10401 00210 9

Quality Care dist inc,
Edison NJ 08817
Made in India

FamilyCare

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When using this product <ul style="list-style-type: none"> do not use in or near eyes do not apply to wounds or damaged skin do not bandage tightly
Stop use and ask doctor if <ul style="list-style-type: none"> condition worsens symptoms last more than 7 days or clear up and occur again within a few days redness or irritation develops
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HOT ICE SOOTHING ANALGESIC

camphor and menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52271-159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.27 g in 227 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	1.14 g in 227 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 934 (UNII: Z135WT9208)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52271-159-00	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/21/2009	

Labeler - Quality Care Distributors LLC (961937112)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	MANUFACTURE

Revised: 7/2010

Quality Care Distributors LLC