

ICY COLD COOL PAIN RELIEVING- menthol, camphor gel
COMPASS HEALTH BRANDS CORP.

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.

ACTIVE INGREDIENTS

MENTHOL 3.9%

CAMPHOR 0.4%

PURPOSE

TOPICAL ANALGESIC

COUNTER IRRITANT

USES

temporary relief of

- Arthritis
- Backache
- Strains/Sprains

WARNINGS

FOR EXTERNAL USE ONLY

Do not use near eyes, mouth, mucus membranes, genitals, cuts, rashes and sores. If contact occurs, flush with cold water. Do not use with heating pad or device, or under bandages. Do not use if pregnant or breastfeeding. Please consult your physician prior to use. Do not apply to wounds or damaged skin.

Stop use and ask a doctor if irritation persists.

Keep out of reach of children. If accidentally ingested, seek medical help or contact a Poison Control Center immediately.

DIRECTIONS

- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
- Rub in thoroughly until gel is absorbed.

INACTIVE INGREDIENTS

Water, Isopropyl Alcohol, Propylene Glycol, Glycerin, Carbomer, Ilex Paraguariensis Leaf Extract, Hydrated Silica, Aminomethyl Propanol, Methyl Paraben, Uncaria Tomentosa Extract, Boswellia Serrata Extract, Camphor for scent.

Thera MED
Professional

Icy Cold

COOL PAIN RELIEVING GEL

3.9% Menthol Ilex Boswelia Uncaria Tomentosa

With Cat's Claw

Provides Temporary Relief of Pain Due to:

- Minor Aches
- Sprains
- Strains
- Bruises
- Strenuous Exercise

16 FL. OZ. (473ML)
NDC# XXXXX-XXX-XX

Drug Facts

Active Ingredient	Purpose
Menthol 3.9%	Topical Analgesic
Camphor 0.4%	Counter Irritant

Uses temporary relief of
 Arthritis Backache Strains/Sprains

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 Middleburg Heights, OH 44130
 Phone 800-376-7263
 Made in USA
 43-LZ1665_00 ©2017



ICY COLD COOL PAIN RELIEVING

menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71323-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.9 g in 100 mL
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F)	
SILICON (UNII: Z4152N8IUJ)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
UNCARIA TOMENTOSA WHOLE (UNII: U6P1SV66LA)	
BOSWELLIA SERRATA WHOLE (UNII: X7B7P649WQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71323-10-1-26	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	
2	NDC:71323-10-1-91	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/22/2017	
3	NDC:71323-10-1-13	88.8 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	
4	NDC:71323-10-1-14	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2017	
5	NDC:71323-10-1-05	5 mL in 1 POUCH; Type 0: Not a Combination Product	03/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	03/22/2017	

Labeler - COMPASS HEALTH BRANDS CORP. (827221698)**Establishment**

Name	Address	ID/FEI	Business Operations
DIVERSIFIED MANUFACTURING CORP		1850 73996	manufacture(71323-10.1)

Revised: 3/2017

COMPASS HEALTH BRANDS CORP.