ARNICA ICE COOLING- camphor menthol gel
Kyron Laboratories (pty) Ltd

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.

Avoid contact with open wounds, eyes or mucus membrains. If excessive skin irritation develops. Wash with water and discontinue use.
Consult a doctor if injuries are severe.

Muscular relief cooling gel

ARNICA OIL
CAMPHOR
WITCH HAZEL
MENTHOL CRYSTALS

CARBOPOL 990
WATER
POLYSORBATE 80
METHYL HYDROXYBENZOATE
PROPYL HYDROXYBENZOATE
TRIETHANOLAMINE 85%

Keep out of reach of children, animals and uniformed persons.
Although this remedy has been extensively tested under a wide variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek advice and notify the registration holder.
This medicine has not been evaluated by the MCC.
This medicine is not intended to diagnose, treat, cure or prevent any disease.

Use only as directed

indications and usage

ARNICA ICE COOLING

camphor menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70674-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	6.0 mg in 100 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
WATER (UNII: 059QF0KO0R)	
WITCH HAZEL (UNII: 101I4J0U34)	
ARNICA MONTANA FLOWER WATER (UNII: U7L2JP51PR)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70674-001-01	475 mg in 1 JAR; Type 0: Not a Combination Product	05/24/2016	
2	NDC:70674-001-02	100 mg in 1 PACKAGE; Type 0: Not a Combination Product	05/24/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/23/2016	

Labeler - Kyron Laboratories (pty) Ltd (568517155)

Establishment

Name	Address	ID/FEI	Business Operations
Kyron Laboratories (pty) Ltd		568517155	manufacture(70674-001)

Revised: 5/2016 Kyron Laboratories (pty) Ltd