MIRACLE ICE ULTRA STRENGTH- menthol and camphor (synthetic) gel
FDN Enterprises,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.

Miracle Ice
Ultra Strength

Drug Facts

Active Ingredient	***Purpose***
Menthol 1%	Topical analgesic
Camphor 0.5%	Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
  - arthritis
  - simple backache
  - strains
  - bruises
  - sport injuries
  - sprains

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 the 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 swallowed, get medical help or contact a Poison Control Center right away.

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.
- children under 2 years of age: ask a doctor

Other information

- Store at room temperature 59°-86°F (15°-30°C).
- Keep jar tightly closed and away from open heat or flame

Inactive ingredients

Aqua, Propylene Glycol, Carbomer, Methyl Salicylate, Sodium Hydroxide, Sodium Methyl Paraben, Sodium Propyle Paraben, CI 14720, CI 16185, CI 42090

Distributed by:
FDN Enterprises, LLC.
Opa Locka, FL 33054

PRINCIPAL DISPLAY PANEL - 227 g Jar Label

FDN Medical®
MIRACLE
ICE

ULTRA STRENGTH

ANALGESIC GEL

NET WT. 8 OZ (227 g)

MIRACLE ICE ULTRA STRENGTH

menthol and camphor (synthetic) gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:60691-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	1 g in 100 g
Camphor (synthetic) (UNII: 5TJD82A1ET) (Camphor (synthetic) - UNII:5TJD82A1ET)	Camphor (synthetic)	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Methyl Salicylate (UNII: LAV5U5022Y)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Methylparaben Sodium (UNII: CR6K9C2NHK)	
Propylparaben Sodium (UNII: 625NNB0G9N)	
Carmoisine (UNII: DR4641L47F)	
Amaranth (UNII: 37RBV3X49K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60691-116-30	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	07/15/2013	

Labeler - FDN Enterprises,LLC (965743867)

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