

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

<i>Active Ingredient</i>	<i>Purpose</i>
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 Propyl 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)



Drug Facts	Purpose Menthol 1%.....Topical analgesic Camphor 0.5%.....Topical analgesic
Active Ingredient	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 • sprains • sport injuries
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 Propyl Paraben, CI 14720, CI 16185, CI 42090
Información sobre este producto	
Ingrediente activo	Menthol 1%.....Analgesico tópico Alcanfor 0.5%.....Analgesico tópico
Usos	para el alivio temporal de dolores y malestares menores en músculos y articulaciones relacionados con: • artritis • dolor de espalda simple • esguinces • contusiones • lesiones deportivas • torceduras
Advertencia:	Uso externo solamente.
No usar	• Con almohadillas eléctricas o calentadores. • No usar en o alrededor de los ojos. • No aplicar sobre heridas o piel abierta. • No apretar los vendajes.
Dejar de usar y consultar a un médico si:	la condición empeora • los síntomas duran más de 7 días o, después de alivarse, vuelven a los pocos días • se produce irritación o enrojecimiento.
Mujeres embarazadas o lactando,	consultar con un especialista de salud antes de usar este producto.
Mantener alejado de los niños.	De ser ingerido, procurar de inmediato asistencia médica o contactar a un centro de control toxicológico.
Modo de uso	Desinfectar el área afectada antes de aplicar este producto. • Adultos y niños mayores de 2 años: aplicar sobre el área afectada no más de 3 a 4 veces al día. • Niños menores de 2 años de edad: consultar con un médico.
Información adicional	guardar a temperatura ambiente 59-86°F (15-30°C) • mantener el envase cerrado herméticamente y alejado de fuentes de calor o las llamas
Excipientes:	Aqua, propilenglicol, carbómero, salicilato de metilo, hidróxido de sodio, metilparabeno sódico, propilparabeno sódico, CI 14720, CI 16185, CI 42090



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: 059QF0K00R)		
	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)

Revised: 9/2013

FDN Enterprises,LLC