

MIRACLE ICE THERAPEUTIC- 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 Therapeutic

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 42090, CI 19140

Distributed by:

FDN Enterprises, LLC.

Opa Locka, FL 33054

PRINCIPAL DISPLAY PANEL - 227 g Jar Label

FDN Medical®

MIRACLE

ICE

THERAPEUTIC

ANALGESIC GEL

NET WT. 8 OZ (227 g)

¿sobre este producto

Propósito
 Analgésico tópico
 Analgésico tópico

el alivio temporal de dolores y malestares menores en
 tificaciones relacionados con: • artritis • dolor de
 • esguinces • Contusiones • lesiones deportivas • torceduras

uso externo solamente.

lillas eléctricas o calentadores.

roducto • No usar en o alrededor de los ojos. • No aplicar
 piel abierta. • No apretar los vendajes.

y consultar a un médico si • la condición empeora
 duran más de 7 días o, después de aliviarse, vuelven a los
 e produce irritación o entorpecimiento.

razadas o lactando, consultar con un especialista de
 usar este producto.

ado de los niños. De ser ingerido, procurar de inmediato
 ca o contactar a un centro de control toxicológico.

• Desinfectar el área afectada antes de aplicar este producto.
 : mayores de 2 años: aplicar sobre el área afectada no más de 3
 • Niños menores de 2 años de edad: consultar con un médico.

dicional • guardar a temperatura ambiente 59°-86° F
 mantener el envase cerrado herméticamente y alejado de
 o las llamas

Agua, propilenglicol, carbómero, salicilato de metilo,
 sodio, metilparabeno sódico, propilparabeno sódico,
 9140

PEEL HERE



Drug Facts

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 • sports injuries • sprains
 • 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 42090, CI 19140

Code No. GUJ/GC/565
 Made in India
 Hecho en la India
 Fabriqué en Inde
 Distributed by:
 Distribuido por:
 FDN Enterprises, LLC
 Opa Locka, FL 33054



FDN Medical®

MIRACLE



THERAPEUTIC • TERAPÉUTICO • THÉRAPEUTIQUE

ANALGESIC GEL • GEL ANALGESICO • GEL ANALGÉSIQUE

NET WT. 8 OZ (227 g)



MIRACLE ICE THERAPEUTIC

menthol and camphor (synthetic) gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60691-117
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: CR6K9C2NHN)	
Propylparaben Sodium (UNII: 625NNB0G9N)	
FD&C Blue No. 1 (UNII: HBR47K3TBD)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60691-117-30	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)