

## **MIRACLE ICE- 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**

#### ***Drug Facts***

<b><i>Active Ingredient</i></b>	<b><i>Purpose</i></b>
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.

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

## PRINCIPAL DISPLAY PANEL - 277 g Jar Label

FDN Medical®

MIRACLE  
ICE

ANALGESIC GEL

NET WT. 8 OZ (277 g)



<b>Drug Facts</b>	<b>Purpose</b> Menthol 1%.....Topical analgesic Camphor 0.5%.....Topical analgesic
<b>Active Ingredient</b>	
<b>Uses</b>	temporarily relieves minor aches and pains of muscles and joints associated with: • arthritis • simple backache • strains • bruises • sport injuries • sprains
<b>Warnings: For external use only</b>	
<b>Do not use</b>	• with other topical pain relievers • with heating pads or heating devices
<b>When using this product</b>	• do not use in or near the eyes • do not apply to wounds or damaged skin • do not bandage tightly
<b>Stop use and ask a doctor if</b>	• condition worsens • symptoms last more than 7 days or clear up and occur again within a few days • redness or irritation develops
<b>If pregnant or breast-feeding</b>	ask a health professional before use.
<b>Keep out of reach of children</b>	if swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b>	• 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
<b>Other information</b>	• Store at room temperature 59-86°F (15-30°C). • Keep jar tightly closed and away from open heat or flame.
<b>Inactive ingredients</b>	Aqua, Propylene Glycol, Carbomer, Methyl Salicylate, Sodium Hydroxide, Sodium Methyl Paraben, Sodium Propyl Paraben, CI 42090.
<b>Information sur le produit</b>	
<b>Substance active</b>	Menthol 1%.....Analgésique topique Camphre 0.5%.....Analgésique topique
<b>Utilisations</b>	permet de soulager temporairement les douleurs mineures des muscles et des articulations dues à : • arthrite • douleur de dos simple • foulures • contusions • lésions sportives • entorses
<b>Avertissement</b>	Usage externe uniquement.
<b>Ne pas utiliser</b>	• avec des coussinets électriques et des appareils chauffants.
<b>Lors de l'utilisation de ce produit</b>	• Ne pas mettre dans ou autour des yeux • Ne pas appliquer sur des blessures ou des plaies ouvertes • Ne pas serrer les bandages.
<b>Cesser l'utilisation et consulter un médecin dans les cas suivants:</b>	• si votre état s'aggrave; • si les symptômes perdurent plus de 7 jours ou si après une amélioration, ils reviennent après quelques jours; • si de intations ou des rougeurs apparaissent.
<b>En cas de grossesse ou d'allaitement</b>	consultez un spécialiste de la santé avant d'utiliser ce produit.
<b>Tenir hors de la portée des enfants</b>	En cas d'ingestion, demander immédiatement une assistance médicale ou contacter un centre antipoison.
<b>Mode d'utilisation</b>	• Désinfecter la zone affectée avant d'appliquer le produit. • Adultes et enfants de plus de deux ans: appliquer sur la zone affectée pas de 3 à 4 fois par jour. • Enfants de moins de 2 ans: demander l'avis d'un médecin.
<b>Informations supplémentaires</b>	• Conserver à température ambiante (entre 15 °C et 30 °C). • Fermer hermétiquement l'emballage et l'éloigner de toute source de chaleur ou des flammes.
<b>Excipients</b>	• eau, propylène glycol, carbomère, salicylate de méthyle, hydroxyde de sodium, méthylparabène de sodium, propylparabène de sodium, CI 42090

# MIRACLE ICE

menthol and camphor (synthetic) gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60691-115
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Menthol</b> (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	1 g in 100 g
<b>Camphor (synthetic)</b> (UNII: 5TJD82A1ET) (Camphor (synthetic) - UNII:5TJD82A1ET)	Camphor (synthetic)	0.5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Methyl Salicylate</b> (UNII: LAV5U5022Y)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>METHYL PARABEN SODIUM</b> (UNII: CR6K9C2NHK)	
<b>PROPYL PARABEN SODIUM</b> (UNII: 625NNB0G9N)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60691-115-30	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