**MIRACLE ICE  ARTHRITIS PAIN RELIEVER- 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.*

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**MIRACLE ICE**
**Arthritis Pain Reliever**

***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, FD&C Blue#1, CI 42090.

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

**PRINCIPAL DISPLAY PANEL - 227 g Jar Label**

**FDN Medical®**

**MIRACLE**
**ICE**

**ARTHRITIS PAIN RELIEVER**

ANALGESIC GEL

NET WT. 8 OZ (227 g)


# MIRACLE ICE ARTHRITIS PAIN RELIEVER

menthol and camphor (synthetic) gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:60691-114 |
| **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) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:60691-114-30 | 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