

# HIELO ARDIENTE- menthol gel

Menper Distributors, Inc.

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## Hielo Ardiente

### Active ingredient

Menthol 1%

### Purpose

Analgesic

### Uses

For the temporary relief of minor aches and pains of muscles and joints associated with simple backaches, arthritis, strains, bruises and sprains.

### Warnings

#### For external use only

- Avoid contact with eyes
- Do not use if condition worsens
- If symptoms persist for more than 5 days or recur, discontinue use and consult a physician
- Do not apply to open wounds or damaged skin
- Do not bandage tightly
- Do not use with heating pads or heating devices

#### Use only as directed

#### Keep out of reach of children.

In case of accidental ingestion, contact a doctor or a Poison Control Center right away.

### Directions

- **Adults and children 12 years of age or older:** Apply to affected area no more than 3 to 4 times daily. Children under 12 years of age, consult a physician
- Cleanse and dry skin. May be used with wet or dry bandages in conjunction with ice packs.

### Inactive ingredients

camphor, carbomer 940, FD&C blue #1, isopropyl alcohol, methylchloro-isothiazolinone, methylisothiazolinone, polysorbate 20, purified water, triethanolamine

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| <b>Drug Facts</b><br><b>Active ingredient</b><br>Menthol 1%<br><b>Purpose</b><br>Analgesic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Uses</b><br>For the temporary relief of minor aches and pains of muscles and joints associated with simple backaches, arthritis, strains, bruises and sprains. |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                   |
| <b>Drug Facts (continued)</b><br><b>Directions</b><br>■ Adults and children 12 years of age and older: Apply to affected area no more than 3 to 4 times daily. Children under 12 years of age, consult a physician<br>■ Cleanse and dry skin. May be used with wet or dry bandages in conjunction with ice packs.<br><b>Other information</b><br>■ store this product between 15°-30°C (59°-86°F)<br><b>Inactive ingredients</b><br>camphor, carbomer 940, FD&C blue #1, isopropyl alcohol, methylchloro-isothiazolinone, methylisothiazolinone, polysorbate 20, purified water, triethanolamine |                                                                                                                                                                   |
| Distributed by:<br>Menper Distributors, Inc.<br>6500 N.W. 25th Avenue<br>Miami, FL 33147<br>www.menperdistributors.com                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                   |
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# HIELO ARDIENTE

menthol gel

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53145-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>                                        | <b>Basis of Strength</b> | <b>Strength</b> |
|---------------------------------------------------------------|--------------------------|-----------------|
| <b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL                  | 1 g in 100 g    |

## Inactive Ingredients

| <b>Ingredient Name</b>                                | <b>Strength</b> |
|-------------------------------------------------------|-----------------|
| <b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)         |                 |
| <b>CARBOMER 940</b> (UNII: 4Q93RCW27E)                |                 |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)         |                 |
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)           |                 |
| <b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN) |                 |
| <b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)       |                 |
| <b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)              |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                       |                 |
| <b>TRIETHANOLAMINE BENZOATE</b> (UNII: M3EN4GC19W)    |                 |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---------------------------------------------------|-----------------------------|---------------------------|
| 1        | NDC:53145-002-01 | 454 g in 1 JAR; Type 0: Not a Combination Product | 02/21/2012                  |                           |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| OTC Monograph Drug        | M017                                            | 02/21/2012                  |                           |

**Labeler** - Menper Distributors, Inc. (101947166)

## Establishment

| <b>Name</b>        | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|--------------------|----------------|---------------|----------------------------|
| World Perfumes Inc |                | 101312044     | manufacture(53145-002)     |