PRIYAL COLD ICE ANALGESIC GEL- menthol gel
Priyal Cosmetics

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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Priyal Cold Ice Gel

*Active Ingredient*
Menthol 2.0%

*Purpose*
Topical Analgesic

*Uses:*
- for temporary relief of minor aches and pains in muscles and joints associated with:
  - simple backaches,
  - strains
  - sprains
  - sports injuries
  - arthritis
  - bruises

*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 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 breastfeeding*
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

**Inactive Ingredients**
ammonium hydroxide, carbomer, cupric sulfate, FD&C Blue No. 1, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water
**Drug Facts**

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menthol 2%</td>
<td>Topical analgesic</td>
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</tbody>
</table>

**Uses** for the temporary relief of minor aches and pains in muscles and joints associated with:
- simple backache
- sprains
- arthritis
- strains
- sports injuries
- bruises

**Warnings**
For external use only

- Do not use with other topical pain relievers
- Do not use with heating pads or heating devices

**When using this product**
- Do not use in or near 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

**Inactive ingredients** ammonium hydroxide, carbomer, cupric sulphate, FD&C blue No.1.
PRIYAL COLD ICE ANALGESIC GEL
menthol gel

Product Information
Product Type: HUMAN OTC DRUG  Item Code (Source): NDC:72822-303
Route of Administration: TOPICAL

Active Ingredient/Active Moiety
<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)</td>
<td>MENTHOL</td>
<td>4.54 g in 227 g</td>
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Inactive Ingredients
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<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>ISOPROPYL ALCOHOL (UNII: ND2M416302)</td>
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<tr>
<td>CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)</td>
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<tr>
<td>CUPRIC SULFATE (UNII: LRX7AJ16DT)</td>
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<tr>
<td>THYMOL (UNII: 3J50XA376E)</td>
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<tr>
<td>FD&amp;C BLUE NO. 1 (UNII: HBR47K3TBD)</td>
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<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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<tr>
<td>SODIUM HYDROXIDE (UNII: 55X04QC321)</td>
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Packaging
<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
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<td>NDC:72822-303-12</td>
<td>227 g in 1 JAR; Type 0: Not a Combination Product</td>
<td>04/08/2019</td>
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Marketing Information
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<tr>
<th>Marketing Category</th>
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<tr>
<td>OTC monograph final</td>
<td>part341</td>
<td>04/08/2019</td>
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**Labeler** - Priyal Cosmetics (675482356)

Revised: 7/2020

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