CARMEX CLASSIC LIP BALM MEDICATED- camphor (synthetic), petrolatum salve
Carma Laboratories, Inc.

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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Carmex Classic Lip Balm Medicated

Drug Facts

Active Ingredients
Camphor 1.70%
White Petrolatum 45.30%

Purpose
External Analgesic
Lip Protectant

Uses
• helps provide relief of symptoms of cold sores and dry lips

Warnings
For external use only

When using this product:
keep out of eyes. Rinse with water to remove.

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

Do not use on:
• deep puncture wounds • serious burns • animal bites

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.

Directions
• apply to lips not more than 3 to 4 times daily
• children under 2 years of age: ask a doctor

Other Information
• this is a personal care item, and should be used by one individual only
• protect this product from excessive heat and direct sun

Inactive Ingredients
lanolin, cetyl esters, theobroma cacao seed butter, paraffin, beeswax, menthol, salicylic acid, phenol, vanillin, flavor

Package Labeling:

**Drug Facts**

- **Active Ingredients**
  - Carmelose 1.75%
  - White Petroleum 46.50%

- **Purpose**
  - External Analgesic
  - Lip Protectant

- **Uses**
  - Helps provide relief of symptoms of cold sores and dry lips

- **Warnings**
  - For external use only
  - When using this product: keep out of eyes. Rinse with water to remove.

- **Other Information**
  - This is a personal care item and should be used by one individual only

- **Inactive Ingredients**
  - Lanolin, cetyl esters, theobroma cacao seed butter, paraffin, beeswax, menthol, salicylic acid, phenol, vanillin, flavor
Product Information

- **Product Type**: HUMAN OTC DRUG
- **Route of Administration**: TOPICAL
- **Item Code (Source)**: NDC:10210-0022

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)</td>
<td>CAMPHOR (SYNTHETIC)</td>
<td>1.77 g in 100 g</td>
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</tbody>
</table>

Drug Facts

- **Active Ingredients**: Camphor 1.7% (External Analgesic), White Petrolatum 45.3% (Lip Protectant)
- **Uses**: Helps relieve symptoms of cold sores and dry lips
- **Warnings**: For external use only. When using this product: Keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if: condition worsens or rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
- **Directions**: Apply 3 to 4 times daily. Children under 2 years of age: ask a doctor.

Inactive Ingredients: lanolin, cetyl esters, theobroma cocoa seed butter, paraffinum liquidum, beeswax, menthol, salicylic acid, phenol, vanillin, flavor.

CARMA LABORATORIES, INC. FRANKLIN, WI 53132
It soothes. It heals. It protects.
## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>LANOLIN (UNII: 7EV65EAW6H)</td>
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</tr>
<tr>
<td>CETYL ESTERS WAX (UNII: D072FFP9GU)</td>
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<tr>
<td>COCOA BUTTER (UNII: 512OYT1CRR)</td>
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<tr>
<td>PARAFFIN (UNII: 800E3H2ZE)</td>
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<tr>
<td>YELLOW WAX (UNII: 2ZA36HS0S2V)</td>
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<tr>
<td>MENTHOL (UNII: L7T10EIP3A)</td>
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<tr>
<td>SALICYLIC ACID (UNII: O414PZ4LPZ)</td>
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<td>PHENOL (UNII: 339NCG44TV)</td>
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<td>VANILLA (UNII: Q74T35078H)</td>
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## Packaging

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<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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<tbody>
<tr>
<td>1</td>
<td>NDC:10210-0022-1</td>
<td>1 in 1 BLISTER PACK</td>
<td>09/26/2016</td>
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</tr>
<tr>
<td>1</td>
<td></td>
<td>7.5 g in 1 JAR; Type 0: Not a Combination Product</td>
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<tr>
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<td>NDC:10210-0022-2</td>
<td>3 in 1 PACKAGE</td>
<td>09/26/2016</td>
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<td>10 g in 1 TUBE; Type 0: Not a Combination Product</td>
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<td>09/26/2016</td>
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## Marketing Information

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<thead>
<tr>
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<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>OTC monograph not final</td>
<td>part348</td>
<td>09/26/2016</td>
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## Labeler

Carma Laboratories, Inc. (006090153)

Revised: 10/2016