CEPACOL SORE THROAT - dyclonine hydrochloride and glycerin liquid
RB Health (US) 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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Cêpacol®
SORE THROAT SPRAY

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyclonine Hydrochloride</td>
<td>Oral pain reliever</td>
</tr>
<tr>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td>Glycerin 33%</td>
<td>Oral demulcent</td>
</tr>
</tbody>
</table>

Uses

for temporary relief of:
- occasional minor irritation, pain, sore mouth, and sore throat
- pain associated with canker sores
- minor discomfort and protection of irritated areas in sore mouth and sore throat

Warnings

Sore throat warning
If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea or vomiting, consult a doctor promptly.

Stop use and ask a doctor or dentist if
- sore mouth symptoms do not improve in 7 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not exceed recommended dosage.

When using this product try to avoid swallowing spray.

Directions

- adults and children 4 years of age and older: Spray 4 times into throat or affected area. Gargle, swish around or allow to remain in place at least 1 minute and then spit out. Repeat up to 4 times daily or as directed by a dentist or doctor. Children 4 to under 12 years of age should be supervised in the use of this product.
- children under 4 years of age: do not use

Other information

- store at room temperature 20-25°C (68-77°F)
- do not freeze
Inactive ingredients

cetylpyridinium chloride, D&C red #33, deionized water, FD&C yellow #6, flavor, menthol, phosphoric acid, poloxamer 338, potassium sorbate, sodium phosphate dibasic, sorbitol

Questions?

1-888-963-3382

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser
Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 63824-781-74

Cēpacol®

SORE THROAT SPRAY

Dyclonine HCl 0.1% · Oral Pain Reliever
Glycerin 33% · Oral Demulcent

Fast Sore Throat Relief
- Instant Acting
- Coats & Soothes

4 FL OZ (118 mL)

SUGAR FREE
chenry
SORE THROAT SPRAY
Dyclonine HCl 0.1% | Oral Pain Reliever
Glycerin 33% | Oral Demulcent

Fast Sore Throat Relief
• Instant Acting
• Coats & Soothes

SUGAR FREE cherry

4 FLOZ (118 mL)

Drug Facts

Active Ingredients
Dyclonine Hydrochloride 0.1% | Oral pain reliever
Glycerin 33% | Oral demulcent

Uses
For temporary relief of:
• occasional minor irritation, pain, sore mouth, and sore throat
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Warnings
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Stop use and ask a doctor or dentist if:
• sore mouth symptoms do not improve in 7 days
• if pregnant or breast-feeding, ask a health professional before use
• keep out of the reach of children.

Directions
• For adults and children 4 years of age and older: Spray 4 times into throat or affected area. Gargle, swallow or allow to remain in place at least 1 minute and then spit out.
• For children under 4 years of age: Use as directed by a dentist or doctor.

Inactive Ingredients
Cetrimide, D&C red #33, deionized water, FD&C yellow #6, flavor, menthol, phosphoric acid, polysorbate 38, potassium sorbate, sodium phosphate dibasic, sorbitol

Questions? 1-800-963-3362
You may also report side effects to this phone number.
**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:63824-781</th>
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<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
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</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th></th>
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<tbody>
<tr>
<td>ORAL</td>
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**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyclonine Hydrochloride (UNII: ZEC193879Q)</td>
<td>Dyclonine Hydrochloride</td>
<td>0.1 g in 100 mL</td>
</tr>
<tr>
<td>Glycerin (UNII: PDC6A3C0OX)</td>
<td>Glycerin</td>
<td>33 g in 100 mL</td>
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**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>cetylpyridinium chloride (UNII: D9OM4SK49P)</td>
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<tr>
<td>D&amp;C red No. 33 (UNII: 9DBA0SBB0L)</td>
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<tr>
<td>water (UNII: 059QF0KO0R)</td>
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<td>FD&amp;C yellow No. 6 (UNII: H77VE93A8)</td>
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<tr>
<td>MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)</td>
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<tr>
<td>phosphoric acid (UNII: E4GA8884NN)</td>
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<td>poloxamer 338 (UNII: F75J2T505)</td>
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<td>potassium sorbate (UNII: 1VP26JZZ4)</td>
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<tr>
<td>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)</td>
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<td>sorbitol (UNII: S06T60A25R)</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>118 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>05/20/2011</td>
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**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
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<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>OTC MONOGRAPH NOT FINAL</td>
<td>part356</td>
<td>05/20/2011</td>
<td></td>
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**Labeler** - RB Health (US) LLC (081049410)