HurriCaine One

Drug Facts

Active Ingredient
Benzocaine 20%

Purpose
Oral Anesthetic

Uses
Uses for the temporary relief of occasional minor irritation and pain associated with sore mouth and throat

Warnings
Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:
• pale, gray, or blue colored skin (cyanosis)
• headache
• rapid heart rate
• shortness of breath
• dizziness or lightheadedness
• fatigue or lack of energy

Allergy alert: Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

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. If sore mouth symptoms do not improve in 7 days, or irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.

Do not use

Do not Use
• if foil pouch has been previously opened
• for teething
• in children under 2 years of age

When using this product
• avoid contact with eyes
Keep out of reach of children.
If more than used for pain is accidently swallowed, get medical help or contact a Poison Control Center Immediately

Directions
• do not exceed recommended dosage

adults and children 2 years of age and older: use up to 4 times daily or as directed by a dentist or doctor
children under 12 years of age: should be supervised in the use of the product
children under 2 years of age: do not use

Other information
• store at 15-30 °C (59-86 °F)

Inactive ingredients
flavor, polyethylene goycol, sodium saccharin

Questions or comments?
1-800-238-4582
M-F: 8:00 a.m. - 4:30 p.m. ET

Principal Display Panel
HurriCaine One 2ct carton
Principal Display Panel
**Hurricane One 25ct carton**

**Hurricane One topical anesthetic spray**

### Product Information

**Product Type**
HUMAN OTC DRUG

**Route of Administration**
DENTAL, PERIODONTAL

**Item Code (Source)**
NDC:0283-0610

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)</td>
<td>BENZOCAINE</td>
<td>200 mg in 1 g</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)</td>
<td>349 mg in 1 g</td>
</tr>
<tr>
<td>SACCHARIN SODIUM (UNII: SB8ZUX40TY)</td>
<td>12 mg in 1 g</td>
</tr>
<tr>
<td>CHERRY (UNII: BUC5I959SW)</td>
<td>439 mg in 1 g</td>
</tr>
</tbody>
</table>

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>Size</td>
</tr>
<tr>
<td>NDC</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>0283-0610-11</td>
<td>2 in 1 BOX</td>
</tr>
<tr>
<td>0283-0610-43</td>
<td>0.492 g in 1 APPLICATOR; Type 0: Not a Combination Product</td>
</tr>
<tr>
<td>0283-0610-26</td>
<td>25 in 1 BOX</td>
</tr>
<tr>
<td>0283-0610-43</td>
<td>0.492 g in 1 APPLICATOR; Type 0: Not a Combination Product</td>
</tr>
</tbody>
</table>

**Marketing Information**

- **Marketing Category**: OTC monograph not final
- **Application Number or Monograph Citation**: part356
- **Marketing Start Date**: 06/15/2010
- **Marketing End Date**: 06/15/2010

**Labeler** - Beutlich Pharmaceuticals LLC (005209325)

**Registrant** - Beutlich Pharmaceuticals LLC (005209325)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIALITY PHARMA MANUFACTURING, LLC</td>
<td></td>
<td>013957125</td>
<td>manufacture(0283-0610)</td>
</tr>
</tbody>
</table>

Revised: 8/2019