HURRICANE TOPICAL ANESTHETIC GEL - benzocaine gel
Beutlich Pharmaceuticals, 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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Drug Facts

Active ingredient
Benzocaine 20%

Purpose
Oral Anesthetic

Uses
for the temporary relief of occasional minor irritation and pain associated with:
  • canker sores
  • sore mouth and throat
  • minor injury of the mouth and gums
  • minor dental procedures
  • minor irritation of the mouth and gums caused by dentures or orthodontic appliances

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 imprinted seal under cap is broken or missing
  • for teething
  • in children under 2 years of age
When using this product

When using this product: avoid contact with eyes

Keep out of reach of children

Keep out of reach of children. If more than used for pain is accidentally 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: apply to the affected area. Allow to remain in place at least 1 minute and then spit out. 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 20°-25° C (68°- 77° F)

Inactive ingredient

flavor, polyethylene glycol, sodium saccharin

Questions or comments?

1-800-238-8542

M-F: 8:00 a.m. to 4:30 p.m. ET

Principal Display Panel
NDC 0283-0293-31
HURRICANE
Topical Anesthetic GEL
20% Benzocaine Oral Anesthetic
WATERMELON
Manufactured for:
Beutlich Pharmaceuticals LLC
Bunnell, FL 32110
Made in the USA
1 oz.

HURRICANE TOPICAL ANESTHETIC GEL
benzocaine gel
**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
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<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:0283-0293</td>
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<table>
<thead>
<tr>
<th>Route of Administration</th>
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<tbody>
<tr>
<td>ORAL, DENTAL, PERIODONTAL</td>
<td>NDC:0283-0293</td>
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**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>Benzocaine</td>
<td>Benzocaine</td>
<td>200 mg in 1 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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<td>Polyethylene Glycol 400</td>
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<tr>
<td>Polyethylene Glycol 3350</td>
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<td>Saccharin Sodium</td>
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**Product Characteristics**

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<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Flavor</th>
<th>Imprint Code</th>
<th>Contains</th>
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<tbody>
<tr>
<td>white (colorless)</td>
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<td></td>
<td></td>
<td>WATERMELON</td>
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**Packaging**

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<th>Item Code</th>
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<th>Marketing End Date</th>
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<td>02/15/1993</td>
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**Marketing Information**

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<th>Marketing End Date</th>
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<tr>
<td>OTC monograph not final</td>
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**Labeler** - Beutlich Pharmaceuticals, LLC (005209325)

**Establishment**

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<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<th>Business Operations</th>
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<td>Dental Technologies Inc.</td>
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<td>manufacture(0283-0293)</td>
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<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Speciality Pharma Manufacturing</td>
<td></td>
<td>013957125</td>
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Revised: 8/2019