

**HURRICAINA TOPICAL ANESTHETIC- benzocaine gel**  
**Beutlich Pharmaceuticals, LLC**

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**HurriCaine Gel LV Syringe - Mint**

**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 the tray seal is broken or missing
- if cap is missing or damaged
- 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 accidentally swallowed, get medical help or contact a Poison Control Center immediately.

### **Directions**

#### **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 ingredients**

- flavor, polyethylene glycol, sodium saccharin

### **Questions or comments?**

**1-800-238-8542**

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

### **Principal Display Panel**

Gel Syringe Unit: 0283-0920-44 1.2g in 1 syringe

Gel Syringe Pack of 4: 0283-0920-29 4 x 1.2g in 1 box.

EXP- **LOT**

**NDC 0283-0920-44**

**HURRICAIN<sup>®</sup>**  
*Topical Anesthetic GEL*  
 20% Benzocaine Oral Anesthetic

**FRESH MINT**

Do not use if cap is missing or damaged. **1.2 g** HSLMT 893 0323



NDC 0283-0920-29

Manufactured for:  
 Beutlich<sup>®</sup> Pharmaceuticals, LLC  
 Bunnell, FL 32110

**FRESH MINT**

**HURRICAIN<sup>®</sup>**  
*Topical Anesthetic GEL*  
 20% Benzocaine Oral Anesthetic



<p><b>Drug Facts</b></p> <p><b>Active ingredient</b> <span style="float: right;"><b>Purpose</b></span>        Benzocaine 20% <span style="float: right;">Oral Anesthetic</span></p> <p><b>Uses</b> for the temporary relief of occasional minor irritation and pain, associated with</p> <ul style="list-style-type: none"> <li>▪ canker sores</li> <li>▪ sore mouth and throat</li> <li>▪ minor injury of the mouth and gums</li> <li>▪ minor dental procedures</li> <li>▪ minor irritation of the mouth and gums caused by dentures or orthodontic appliances</li> </ul> <p><b>Warnings</b></p> <p><b>Methemoglobinemia warning:</b> 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:</p> <ul style="list-style-type: none"> <li>▪ pale, gray, or blue colored skin (cyanosis)</li> <li>▪ headache</li> <li>▪ rapid heart rate</li> <li>▪ shortness of breath</li> <li>▪ dizziness or lightheadedness</li> <li>▪ fatigue or lack of energy</li> </ul> <p><b>Allergy alert:</b> Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings (continued)</b></p> <p><b>Sore throat warning:</b> 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 if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>▪ if cap is missing or damaged</li> <li>▪ for teething</li> <li>▪ in children under 2 years of age</li> </ul> <p><b>When using this product</b> avoid contact with eyes</p> <p><b>Keep out of reach of children.</b> If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately.</p> <p><b>Directions</b></p> <table style="width: 100%; border: none;"> <tr> <td style="border: none; width: 50%;">adults and children 2 years of age and older</td> <td style="border: none; width: 50%;">do not exceed recommended dosage 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.</td> </tr> <tr> <td style="border: none;">children under 12 years of age</td> <td style="border: none;">should be supervised in the use of the product</td> </tr> <tr> <td style="border: none;">children under 2 years of age</td> <td style="border: none;">do not use</td> </tr> </table>	adults and children 2 years of age and older	do not exceed recommended dosage 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	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b>        store at 20-25 °C (68-77 °F)</p> <p><b>Inactive ingredients</b>        flavor, polyethylene glycol, sodium saccharin</p> <p><b>Questions or comments?</b>        1-800-238-6542        M-F: 8:00 a.m. – 4:30 p.m., ET</p> <p><b>Please retain Drug Facts for future reference.</b>        HurriCaine<sup>®</sup> is a registered trademark of Beutlich Pharmaceuticals, LLC, 7775 S. US Hwy 1, Suite H, Bunnell, FL 32110. www.beutlich.com</p> <p style="text-align: center;">LOT EXP-</p> <p style="text-align: center;">No UV Coating in this Area</p> <p style="text-align: center;">7 23797 92029 9</p>
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- KIT CONTAINS:**
- 4 x 1.2 g Prefilled Syringes
  - 4 Dispensing Tips
  - Instruction for use

## HURRICAIN<sup>®</sup> TOPICAL ANESTHETIC

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-0920
<b>Route of Administration</b>	ORAL, DENTAL, PERIODONTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0920-29	4 in 1 BOX	03/15/2023	
1	NDC:0283-0920-44	1.2 g in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/31/2021	

**Labeler** - Beutlich Pharmaceuticals, LLC (005209325)**Registrant** - Beutlich Pharmaceuticals, LLC (005209325)**Establishment**

Name	Address	ID/FEI	Business Operations
Dental Technologies, Inc.		148312838	manufacture(0283-0920)