

**HURRICAINA TOPICAL ANESTHETIC- 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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**HurriCaine Gel LV Syringe - Pina Colada**

**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**

Manufactured for:  
Beutlich Pharmaceuticals, LLC  
Bunnell, FL 32110  
NDC 0283-1820-34



**PIÑA COLADA**

**HURRICAINÉ**  
20% Benzocaine Oral Anesthetic  
Topical Anesthetic GEL

**HURRICAINÉ**  
Topical Anesthetic GEL  
20% Benzocaine Oral Anesthetic

Drug Facts	
<b>Active ingredient</b> Benzocaine 20%	<b>Purpose</b> .....Oral Anesthetic
<b>Uses</b> for the temporary relief of occasional minor irritation and pain, associated with <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>	
<b>Warnings</b> <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: <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> <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.	

Drug Facts (continued)	
<b>Warnings (continued)</b> <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. <b>Do not use</b> <ul style="list-style-type: none"> <li>• if tray seal is broken or missing</li> <li>• for teething</li> <li>• in children under 2 years of age</li> </ul> <b>When using this product</b> avoid contact with eyes <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.	
<b>Directions</b> 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	

Drug Facts (continued)	
<b>Other information</b> store at 20-25 °C (68-77 °F)	
<b>Inactive ingredients</b> flavor, polyethylene glycol, sodium saccharin	
<b>Questions or comments?</b> 1-800-238-8542 M-F: 8:00 a.m. - 4:30 p.m. ET	
<b>Please retain Drug Facts for future reference.</b> Hurricane® is a registered trademark of Beutlich Pharmaceuticals, LLC, 7775 S. US Hwy 1, Suite H, Bunnell, FL 32110. www.beutlich.com	
LOT	No UV Coating in this Area
EXP	

HSPPC 891 1120

Gel Syringe Unit: 0283-1820-43 1.5g in 1 syringe  
Gel Syringe Pack of 4: 0283-1820-34 4 x 1.5g in 1 box.



**HURRICAINÉ TOPICAL ANESTHETIC**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-1820
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**Route of Administration** ORAL, DENTAL, PERIODONTAL

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COCONUT (Pina Colada flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-1820-34	4 in 1 BOX	01/31/2021	
1	NDC:0283-1820-43	1.5 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 not final	part356	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(0283-1820)