

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

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**HurriCaine Unit Dose Gel and Swab - Cherry**

**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 product film is punctured 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**

NDC 0283-0871-45

0.5 g

Manufactured for:  
Beutlich® Pharmaceuticals, LLC  
Bunnell, FL 32110

UDGC 898 1220

**HURRICAINÉ**<sup>®</sup>  
Unit-Dose Topical Anesthetic Gel  
20% Benzocaine Oral Anesthetic  
ORIGINAL WILD CHERRY



HurriCaine Unit Dose Gel Wild Cherry 0.5g with Swab: 0283-0871-45

60ct HurriCaine Unit Dose Gel Wild Cherry 0.5g with Swab: 0283-0871-59

Please retain Drug Facts for future reference.

<b>Drug Facts</b>	<b>Purpose</b> Benzocaine 20%.....Oral Anesthetic
<b>Active ingredient</b>	
<b>Uses</b>	For the temporary relief of occasional minor irritation and pain, associated with <ul style="list-style-type: none"> <li>• cancer sores</li> <li>• sore mouth and throat</li> <li>• minor injury of the mouth and gums caused by dentures or orthodontic appliances</li> <li>• minor irritation of the mouth and gums caused by dentures or orthodontic appliances</li> </ul>
<b>Warnings</b>	<b>Mathemoglobinemia 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, butabaine, benzocaine, or other "caine" anesthetics. <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>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
<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

**Drug Facts (continued)**  
**Warnings (continued)**  
Do not use - If product (in) is punctured or damaged for use - If 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.

**Beutlich**  
PHARMACEUTICALS LLC  
Since 1958  
7775 S. US Hwy 1, Suite H,  
Bunnell, FL 32110.  
www.beutlich.com

HurriCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC.  
UDGC 898 1220

Manufactured for  
Beutlich® Pharmaceuticals, LLC  
Bunnell, FL 32110

**HURRICAINÉ**<sup>®</sup>  
Unit-Dose Topical Anesthetic Gel  
20% Benzocaine Oral Anesthetic  
ORIGINAL WILD CHERRY

60 Unit Dose Topical Anesthetic Gel  
0.017 fl. oz., (0.5 g) each

No UV Coating in this Area

LOT  
EXP. DATE

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# HURRICAINÉ TOPICAL ANESTHETIC

benzocaine gel

## Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0283-0871

**Route of Administration** 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>	brown (amber)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0871-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-0871-45	0.5 g in 1 CUP, UNIT-DOSE; Type 1: Convenience Kit of Co-Package		

### 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
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0871) , pack(0283-0871)

### Establishment

Name	Address	ID/FEI	Business Operations
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Centrix Inc		053707303	label(0283-0871)
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## Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies, Inc.		148312838	manufacture(0283-0871)

Revised: 1/2025

Beutlich Pharmaceuticals, LLC