

**HURRICAINES- topical anesthetic spray**  
**Beutlich Pharmaceuticals LLC**

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**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 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: 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 glycol, 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

Please retain Drug Facts for future reference

## Drug Facts

**Active ingredient** Benzocaine 20% **Purpose** Oral Anesthetic

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

### Warnings

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## Drug Facts (continued)

### Warnings (continued)

#### 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 accidentally swallowed, get medical help or contact a Poison Control Center immediately.

### Directions

age	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 glycol, sodium saccharin

### Questions or comments?

1-800-238-9542

M-F: 8:00 a.m. – 4:30 p.m. ET

## DIRECTIONS



NDC 0283-0610-11

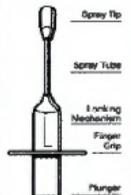
Manufactured for  
Beutlich® Pharmaceuticals, LLC  
Bunnell, FL 32110



# HURRICaine ONE®

Unit-Dose Non-Aerosol Spray  
20% Benzocaine Oral Anesthetic  
**ORIGINAL WILD CHERRY FLAVOR**

### PRODUCT DIAGRAM



2 Unit-Dose Non-Aerosol Spray – 0.017 fl. oz. (0.5 mL) each

Enclosed Applicator

HurriCaine ONE is a trademark of  
Beutlich Pharmaceuticals, LLC.  
7775 S. US Hwy 1, Suite H, Bunnell, FL 32110  
www.beutlich.com

LOT

EXP



0283-0610-11

HO28 598 0725

## Principal Display Panel

HurriCaine One 25ct carton

**1 UNIT DOSE AND ONLY**

Please retain Drug Facts for future reference

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Benzocaine 20%	Oral Anesthetic
<b>Uses:</b> For the temporary relief of occasional minor irritation and pain associated with sore mouth and throat.	
<b>Warnings</b>	
<b>Metabolism/warnings:</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 skin (not normally)</li> <li>• headache</li> <li>• rapid heart rate</li> <li>• shortness of breath</li> <li>• dizziness or lightheadedness</li> <li>• tingles or lack of energy</li> </ul>	
<b>Other warnings:</b> Do not use if you have a history of allergy to local anesthetics such as procaine, tetracaine, benzocaine, or other "caine" anesthetics.	
<b>Sore throat warning:</b> If sore throat is severe, persists for more than 7 days, is accompanied or followed by fever, headache, rash, swelling, lesions or white patches in your mouth, or if sore mouth symptoms do not improve in 7 days, or if it involves pain, or redness persists or worsens, see your dentist or doctor promptly.	
<b>Do not use:</b>	
<ul style="list-style-type: none"> <li>• if the pouch has been previously opened</li> <li>• for soothing</li> <li>• in children under 2 years of age</li> </ul>	
When using this product avoid contact with eyes.	
Keep out of reach of children. If more than 1 use for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions:</b> Do not exceed recommended dosage.	
age	dose
adults and children 7 years of age and older	use up to 4 times daily or as directed by a dentist or doctor
children under 15 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 1-30°C (68-86°F).	
<b>Inactive ingredients:</b> flaxol, sodium hydroxyethyl, sodium saccharin	
<b>Questions or comments?</b> 1-800-836-6546. NDC: 0283-0610-26. © 2011, BPC, Inc., CT.	

**HURRICaine ONE**

Unit-Dose Non-Aerosol Spray  
20% Benzocaine Oral Anesthetic  
ORIGINAL WILD CHERRY FLAVOR



**1 UNIT DOSE AND ONLY**

HurriCaine ONE is a registered trademark of Beutlich Pharmaceuticals, LLC.  
7775 S. US Hwy 1, Suite H, Bunnell, FL 32110, www.beutlich.com

H0258 596 0725



Beutlich Pharmaceuticals, LLC  
Bunnell, FL 32110  
Manufacturer

25 Unit-Dose Non-Aerosol Sprays  
0.017 fl. oz. (0.5 mL) each

**1 UNIT DOSE AND ONLY**

**HURRICaine ONE**  
Unit-Dose Non-Aerosol Spray  
20% Benzocaine Oral Anesthetic  
ORIGINAL WILD CHERRY FLAVOR



**HURRICaine ONE**  
Unit-Dose Non-Aerosol Spray  
20% Benzocaine Oral Anesthetic  
ORIGINAL WILD CHERRY FLAVOR

NDC 0283-0610-26

**DIRECTIONS**

- Tear at notch to open pouch. Remove HurriCaine ONE® from pouch.
- To unlock, turn clockwise.
- Grasp HurriCaine ONE firmly by placing your index and middle fingers on the finger grip and position your thumb against the base of the plunger.
- Position patient with mouth open. Aim spray tip toward the back of patient's throat.
- Apply firm pressure to the plunger by pushing your thumb forward to initiate the spray action. Instruct patient to swallow 1st time. Anesthesia is accomplished within 30 seconds and lasts approximately 15 minutes.

**HURRICaine**

topical anesthetic spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-0610
<b>Route of Administration</b>	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)	349 mg in 1 g
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	12 mg in 1 g
<b>CHERRY</b> (UNII: BUC5I9595W)	439 mg in 1 g

### Product Characteristics

<b>Color</b>		<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:0283-0610-11	2 in 1 BOX	04/01/2016	
1	NDC:0283-0610-43	0.492 g in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:0283-0610-26	25 in 1 BOX	04/01/2016	
2	NDC:0283-0610-43	0.492 g in 1 APPLICATOR; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	06/15/2010	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0610) , pack(0283-0610)

Revised: 12/2025

Beutlich Pharmaceuticals LLC