

**HURRICAINE- 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



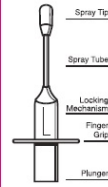
# HURRICAINÉ ONE®

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

**Beutlich**  
PHARMACEUTICALS, LLC  
Since 1954

Manufactured for  
Beutlich® Pharmaceuticals, LLC  
Bunnell, FL 32110

PRODUCT DIAGRAM



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

Please retain Drug Facts for future reference

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**Drug Facts (continued)**

**Warnings (continued)**

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**Questions or comments?**  
1-800-238-8542  
M-F: 8:00 a.m. - 4:30 p.m. ET

HO2B 595 0518

0283-0610-11



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

**Principal Display Panel**



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>	
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age	dose
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<b>Other information</b> • store at 15-30 °C (59-86 °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	

## DIRECTIONS



Tear at notch to open pouch. Remove HurriCaine ONE® from pouch.



To unlock, turn clockwise.



Grasp HurriCaine ONE firmly by placing your first and second fingers on the finger grip, while your thumb is touching the base of the plunger.



Position patient with mouth open. Aim spray tip toward the back of patient's throat.



Apply firm pressure to plunger by pushing thumb forward to initiate spray action. Instruct patient to swallow 1-2 times. Anesthesia is accomplished within 30 seconds and lasts approximately 15 minutes.

## HurriCaine One 25ct carton

### HURRICAINÉ

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>	PERIODONTAL, DENTAL		

#### 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: 2/2024

Beutlich Pharmaceuticals LLC