

# **HURRICAINE TOPICAL ANESTHETIC GEL- 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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### **PC Unit Dose Gel**

### **Drug Facts**

#### **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 product film is punctured or damaged
- for teething
- in children under 2 years of age

## **When using this product**

**When using this product:** avoid contact with eyes

## **Keep out of reach of children**

**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

## **Storage and Handling**

- 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. to 4:30 p.m. ET

## **Principal Display Panel**

NDC 0283-0886-45

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

UDPCG 833 1220

**HURRICAINÉ®**  
 Unit Dose Topical Anesthetic Gel  
 20% Benzocaine Oral Anesthetic  
 PIÑA COLADA



Do not use if product film is punctured or damaged.

HurriCaine Unit Dose Gel Pina Colada 0.5g with Swab: 0283-0886-45

60ct HurriCaine Unit Dose Gel Pina Colada 0.5g with Swab: 0283-0886-59



**HURRICAINÉ®**  
 Unit Dose Topical Anesthetic Gel  
 20% Benzocaine Oral Anesthetic  
 PIÑA COLADA

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

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

Beutlich  
 PHARMACEUTICALS, LLC  
 Since 1954  
 7776 S. US Hwy 1, Suite H,  
 Bunnell, FL 32110,  
 www.beutlich.com

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

UDGPRC 889 1220

**FPD**  
 7 23797 886559 5

LOT  
 No LV  
 Coating in this Area

Please retain Drug Facts for future reference.

<p><b>Drug Facts</b></p> <p><b>Active Ingredient</b>          Benzocaine 20%.....Oral Anesthetic</p> <p><b>Purpose</b></p> <p><b>Uses</b> 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 throat and gums caused by dentures or orthodontic appliances</p> <p><b>Warnings</b></p> <p><b>Major adverse reactions:</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:          • pale, gray, or blue colored skin (cyanosis) • headache • rapid heart rate          • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy</p> <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>Some throat warnings:</b> If some 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 some 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>Drug Facts (continued)</b></p> <p><b>Warnings (continued)</b>          Do not use • if product film is punctured or damaged          • for teething • in children under 2 years of age</p> <p><b>When using this product avoid contact with eyes</b></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> do not exceed recommended dosage          adults and teens apply to the affected area. Allow to dry. Rub gently. Do not use more than 4 times daily or as directed by a dentist or doctor.</p> <p>children under 12 years of age should be supervised in the use of the product</p> <p>children under 2 years of age do not use</p> <p><b>Other Information</b>          store at 20-25 °C (68-77 °F)</p> <p><b>Inactive ingredients</b>          Inver, polyethylene glycol, sodium saccharin</p> <p><b>Questions or comments?</b>          1-800-238-8842          M-F: 8:00 a.m. - 4:30 p.m., ET</p>
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## HURRICAINÉ TOPICAL ANESTHETIC GEL

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-0886
<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>	yellow (yellow to pale orange)	<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:0283-0886-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-0886-45	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 not final	part356	08/15/1986	

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

Name	Address	ID/FEI	Business Operations
Dental Technologies, Inc.		148312838	manufacture(0283-0886)

**Establishment**

Name	Address	ID/FEI	Business Operations
Centrix Inc		053707303	label(0283-0886)

**Establishment**

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0886) , pack(0283-0886)

Revised: 3/2023

Beutlich Pharmaceuticals, LLC