

# **HURRICAINA 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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### **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

## **Other information**

### **Other information**

store at 20°-25° C (68°- 77° F)

## **Inactive ingredient**

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**

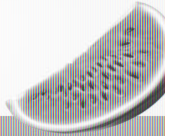
NDC 0283-0293-45

0.5 g

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

UD38W 920 1220

**HURRICAINÉ**<sup>®</sup>  
Unit Dose Topical Anesthetic Gel  
20% Benzocaine Oral Anesthetic  
**WATERMELON**



HurriCaine Unit Dose Gel Watermelon 0.5g with Swab: 0283-0293-45

60ct HurriCaine Unit Dose Gel Watermelon 0.5g with Swab: 0283-0293-59



**HURRICAINÉ**<sup>®</sup>  
Unit Dose Topical Anesthetic Gel  
20% Benzocaine Oral Anesthetic  
**WATERMELON**

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

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

UD38W 920 1220

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

Beutlich  
PHARMACEUTICALS, LLC  
Since 1954  
7775 S. US Hwy 1, Suite H,  
Bunnell, FL 32110,  
www.beutlich.com

LOT: No UV  
EXP: Coating in this Area

FPO 23797 29359

Please retain Drug Facts for future reference.

<b>Drug Facts</b>	<b>Purpose</b>
Active ingredient Benzocaine 20%.....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. Do not use if you have a history of allergy to local anesthetics such as procaine, tetracaine, benzocaine, or other "caine" anesthetics. <ul style="list-style-type: none"> <li>■ cold, 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>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 persists or worsens, see your dentist or doctor promptly.	

<b>Drug Facts (continued)</b> <b>Warnings (continued)</b> Do not use: <ul style="list-style-type: none"> <li>■ if product film is punctured or damaged</li> <li>■ for teething</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 used for pain relief, contact your dentist, doctor, or Poison Control Center immediately.	<b>Directions</b> do not exceed recommended dosage adults and children 2 years and older: apply to the affected area. Allow to remain in place at least 1 minute and or apply and older: Use up to 4 times daily or as directed by a dentist or doctor. children under 2 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> 1-800-238-6542 M-F: 8:00 a.m. - 4:30 p.m. ET	

## HURRICAINÉ TOPICAL ANESTHETIC GEL

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-0293
<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>	white (colorless)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WATERMELON	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0293-53	60 in 1 BOX	01/31/2021	01/31/2023
1	NDC:0283-0293-45	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	02/15/1993	

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

Name	Address	ID/FEI	Business Operations
Dental Technologies Inc.		148312838	manufacture(0283-0293)

Revised: 1/2023

Beutlich Pharmaceuticals, LLC