

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

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**HurriCaine Gel LV Syringe - Wild 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 tray seal is broken or missing
- 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**

EXP. LOT

NDC 0283-0520-44

**HURRICAINE**<sup>®</sup>

Topical Anesthetic GEL  
20% Benzocaine Oral Anesthetic



**ORIGINAL WILD CHERRY**

Do not use if cap is missing or damaged.

1.2 g

HSLC 892 0323

Gel Syringe Unit: 0283-0520-44 1.2g in 1 syringe

Gel Syringe Pack of 4: 0283-0520-44 4 x 1.2g in 1 box.

Manufactured for:  
Beutlich Pharmaceuticals, LLC  
Bunnell, FL 32110

NDC 0283-0520-29



**ORIGINAL WILD CHERRY**

**HURRICAINE**<sup>®</sup>

Topical Anesthetic GEL  
20% Benzocaine Oral Anesthetic

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Topical Anesthetic GEL

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**Drug Facts**

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Benzocaine 20% 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  
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 • headache • rapid heart rate • shortness of breath  
 • dizziness or lightheadedness • fatigue or lack of energy

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**Drug Facts (continued)**

**Warnings (continued)**

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**Drug Facts (continued)**

**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

**Please retain Drug Facts for future reference.**  
 HurriCaine<sup>®</sup> is a registered trademark of Beutlich Pharmaceuticals, LLC, 7775 S. US Hwy 1, Suite H, Bunnell, FL 32110, www.beutlich.com

LOT  
EXP

No UV  
Coating in this Area



HSPC 888 0923

- KIT CONTAINS:**
- 4 x 1.2 g Prefilled Syringes
  - 4 Dispensing Tips
  - Instruction for use

# HURRICAINA TOPICAL ANESTHETIC

benzocaine gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-0520
<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>	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:0283-0520-29	4 in 1 BOX	03/15/2023	
1	NDC:0283-0520-44	1.2 g in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

## 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**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Dental Technologies, Inc.		148312838	manufacture(0283-0520)

Revised: 11/2023

Beutlich Pharmaceuticals, LLC