

**HURRICAINE TOPICAL ANESTHETIC- benzocaine spray**  
**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.

**Flammable.** Do not use near fire or flame. Avoid smoking during use.

**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**

- for teething
- in children under 2 years of age

## **When using this product**

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- avoid spraying in eyes
- do not store at temperature above 49 °C (120 °F)
- do not puncture or incinerate. Contents under pressure.
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

## **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
- firmly insert extension tube into spray can valve and ensure it fits securely into the actuator opening
- position the extension tube 1-2 inches from the affected area
- spray 1/2 second (press and immediately release actuator)
- repeat once if necessary
- anesthesia is accomplished in approximately 20 seconds

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

## **Inactive ingredients**

flavor, hydrocarbon propellant (isobutane and propane), polyethylene glycol, sodium saccharin

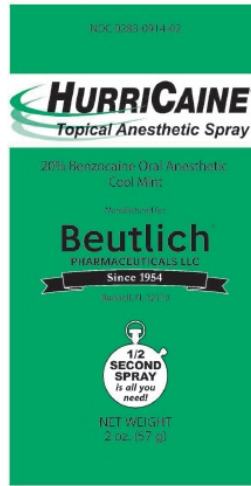
## **Questions or comments?**

1-800-238-8542

M-F: 8:00 a.m. - 4:30 p.m. ET

Principal Display Panel

Cool Mint Spray NDC 0283-0914-02

<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Benzocaine 20%.....Oral Anesthetic</p> <p><b>Uses</b> for the temporary relief of occasional minor irritation and pain, associated with:</p> <ul style="list-style-type: none"> <li>• canker sores • 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> <p>OPEN HERE</p>  <p>7 23797 91402 1</p> <p>LOT HS1220M EXP 12/2023</p> <p>HSLM 777 1120</p>	 <p>NDC 0283-0914-02</p> <p><b>HURRICAINÉ</b> Topical Anesthetic Spray</p> <p>20% Benzocaine Oral Anesthetic Cool Mint</p> <p>Manufactured by <b>Beutlich</b> PHARMACEUTICALS LLC Since 1954</p> <p>NET WEIGHT 2.0z (57 g)</p> <p>1/2 SECOND SPRAY is all you need!</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings (continued)</b> When using this product</p> <ul style="list-style-type: none"> <li>• avoid spraying in eyes</li> <li>• do not store at temperature above 49 °C (120 °F)</li> <li>• do not puncture or incinerate. Contents under pressure.</li> <li>• use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.</li> </ul> <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></p> <ul style="list-style-type: none"> <li>• do not exceed recommended dosage</li> <li>• firmly insert extension tube into spray can valve and ensure it fits securely into the actuator opening</li> <li>• position the extension tube 1-2 inches from the affected area</li> <li>• spray 1/2 second (press and immediately release actuator)</li> <li>• repeat once if necessary</li> <li>• anesthesia is accomplished in approximately 20 seconds</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings (continued)</b></p> <p><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. Stop use and seek immediate medical attention if you or a child in your care develops:</p> <ul style="list-style-type: none"> <li>• pale, gray, or blue colored skin (cyanosis)</li> <li>• headache • rapid heart rate</li> <li>• shortness of breath</li> <li>• dizziness or lightheadedness</li> <li>• fatigue or lack of energy</li> </ul> <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>Flammable. Do not use near fire or flame. Avoid smoking during use.</b></p> <p><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 persist or worsens, see your dentist or doctor promptly.</p> <p><b>Do not use</b> • for teething • in children under 2 years of age</p>
<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose</b> Benzocaine 20%.....Oral Anesthetic</p> <p><b>Uses</b> for the temporary relief of occasional minor irritation and pain, associated with:</p> <ul style="list-style-type: none"> <li>• canker sores • 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> <p>OPEN HERE</p>  <p>7 23797 91402 1</p> <p>LOT HS1220M EXP 12/2023</p> <p>HSLM 777 1120</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions (continued)</b></p> <p>adults and children Use up to 4 times daily or as directed by a dentist or doctor.</p> <p>2 years of age and older</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>Inactive ingredients</b> flavor, hydrocarbon propellant (isobutane and propane), polyethylene glycol, sodium saccharin</p> <p><b>Questions or comments?</b> 1-800-238-8542 M-F: 8:00 a.m. - 4:30 p.m. ET</p> <p>Manufactured for: <b>Beutlich</b> PHARMACEUTICALS LLC Since 1954</p> <p>7775 S. US Hwy 1, Suite H Bunnell, FL 32110 www.beutlich.com</p>	<p>Hurricane® Topical Anesthetic is available in the following dosage forms:</p> <p><b>Gel</b> – 1 oz. bottle</p> <ul style="list-style-type: none"> <li>• Original Wild Cherry • Watermelon</li> <li>• Piña Colada • Fresh Mint</li> <li>• Strawberry</li> </ul> <p><b>Liquid</b> – 1fl. oz. bottle</p> <ul style="list-style-type: none"> <li>• Original Wild Cherry • Piña Colada</li> </ul> <p><b>Snap -n- Go™ Swabs</b> – Box of 72 swabs</p> <ul style="list-style-type: none"> <li>• Original Wild Cherry</li> </ul> <p><b>Spray</b> – 2 oz. spray and 1 disposable extension tube (for single patient use)</p> <ul style="list-style-type: none"> <li>• Cool Mint • Original Wild Cherry</li> </ul> <p><b>Spray Kit</b> – for multiple patient use*</p> <ul style="list-style-type: none"> <li>• Cool Mint</li> <li>• 2 oz. spray and 100 individually sealed disposable extension tubes</li> <li>• Original Wild Cherry</li> <li>• 2 oz. spray and 200 disposable extension tubes</li> </ul> <p>*Additional extension tubes are available for purchase.</p> <ul style="list-style-type: none"> <li>• Green individually sealed disposable extension tubes – Box of 100</li> <li>• Red disposable extension tubes – Box of 200</li> </ul> <p><b>Hurricane ONE® Unit Dose Non-Aerosol Spray</b> Boxes of 2 each or 25 each</p> <ul style="list-style-type: none"> <li>• Original Wild Cherry</li> </ul> <p>Hurricane and Hurricane ONE are registered trademarks of Beutlich® Pharmaceuticals, LLC. Snap -n- Go is a trademark of Beutlich Pharmaceuticals, LLC.</p>	 <p>NDC 0283-0914-02</p> <p><b>HURRICAINÉ</b> Topical Anesthetic Spray</p> <p>20% Benzocaine Oral Anesthetic Cool Mint</p> <p>Manufactured by <b>Beutlich</b> PHARMACEUTICALS LLC Since 1954</p> <p>NET WEIGHT 2.0z (57 g)</p> <p>1/2 SECOND SPRAY is all you need!</p>

**HURRICAINÉ TOPICAL ANESTHETIC**  
benzocaine spray

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-0914
<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>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>MINT</b> (UNII: FV98Z8GITP)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0914-02	59.7 g in 1 CAN; Type 0: Not a Combination Product	09/01/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/01/2014	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Precise Packaging, LLC		194325999	manufacture(0283-0914)

Revised: 7/2021

Beutlich Pharmaceuticals, LLC