

HURRICAINA TOPICAL ANESTHETIC- benzocaine spray
Beutlich Pharmaceuticals, LLC

HurriCaine Spray
Original 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.

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

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- for teething
- in children under 2 years of age

When using this product

When using this product

- 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

Product Label

HurriCaine Spray - Original Wild Cherry 2oz

<p>Drug Facts (continued)</p> <p>Warnings (continued)</p> <p>When using this product</p> <ul style="list-style-type: none"> 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. <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> 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 	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>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:</p> <ul style="list-style-type: none"> pale, gray, or blue colored skin (cyanosis) headache rapid heart rate shortness of breath dizziness or lightheadedness fatigue or lack of energy <p>Allergy alert: Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.</p> <p>Flammable. Do not use near fire or flame. Avoid smoking during use.</p> <p>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 throat symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.</p> <p>Do not use</p> <ul style="list-style-type: none"> for teething in children under 2 years of age 	<p>Drug Facts</p> <p>Active ingredient Purpose Benzocaine 20%.....Oral Anesthetic</p> <p>Uses for the temporary relief of occasional minor irritation and pain, associated with:</p> <ul style="list-style-type: none"> 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 <p>OPEN HERE</p>  <p>LOT: </p> <p>EXP: </p> <p>H50 145 0225</p>	<p>Drug Facts (continued)</p> <p>Directions (continued)</p> <table border="1"> <tr> <td>adults and children 2 years of age and older</td> <td>Use up to 4 times daily or as directed by a dentist or doctor.</td> </tr> <tr> <td>children under 12 years of age</td> <td>should be supervised in the use of the product</td> </tr> <tr> <td>children under 2 years of age</td> <td>do not use</td> </tr> </table> <p>Inactive ingredients flavor, hydrocarbon propellant (isobutane and propane), polyethylene glycol, sodium saccharin</p> <p>Questions or comments? 1-800-238-8542 M-F: 8:00 a.m. – 4:30 p.m. ET</p>	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
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<p>Effective and Fast-acting!</p> <p>Manufactured for: Beutlich® Pharmaceuticals, LLC 7775 S. US Hwy 1, Suite H Bunnell, FL 32110 www.beutlich.com</p> <p>HurriCaine® is a registered trademark of Beutlich® Pharmaceuticals, LLC.</p>	<p>NDC 0283-0679-02</p> <p>HURRICAINÉ Topical Anesthetic Spray</p> <p>20% Benzocaine Oral Anesthetic ORIGINAL Wild Cherry</p>  <p>NET WEIGHT 2 oz. (57 g)</p>
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Drug Facts

Active Ingredient **Purpose**
Benzocaine 20% Oral Anesthetic

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• minor injury of the mouth and gums • minor dental procedures
• minor irritation of the mouth and gums caused by dentures or orthodontic appliances

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Drug Facts (continued)

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Inactive ingredients
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Questions or comments?
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M-F: 8:00 a.m. - 4:30 p.m. ET

Please retain Drug Facts for future reference.

Manufactured for:
Beutlich® Pharmaceuticals, LLC
7775 S. US Hwy 1, Suite H
Bunnell, FL 32110
www.beutlich.com

HURRICAINÉ®
Topical Anesthetic SPRAY KIT
20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY

NDC 0283-0679-60

Contents:
1 HurriCaine® Topical Anesthetic Spray – 2 oz. (57 g)
200 Disposable Extension Tubes

HurriCaine is a registered trademark of Beutlich® Pharmaceuticals, LLC.
7775 S. US Hwy 1, Suite H, Bunnell, FL 32110.
www.beutlich.com HSK 37 0325

LOT: _____
EXP: _____
Spot AQ



HURRICAINÉ TOPICAL ANESTHETIC

benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0679
Route of Administration	ORAL, DENTAL, PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	200 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			349 mg in 1 g	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			12 mg in 1 g	
CHERRY (UNII: BUC5I9595W)			439 mg in 1 g	
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0679-02	59.7 g in 1 CAN; Type 0: Not a Combination Product	06/15/1979	
2	NDC:0283-0679-60	1 in 1 BOX	06/15/1979	
2	NDC:0283-0679-02	59.7 g in 1 CAN; 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	06/15/1979		

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment			
Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	pack(0283-0679)

Establishment			
Name	Address	ID/FEI	Business Operations
TRI-PAC, INC.		020844956	manufacture(0283-0679)