

HURRICAINA TOPICAL ANESTHETIC- benzocaine gel
Beutlich Pharmaceuticals, LLC

HurriCaine Gel - Cherry 1oz

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

Allergy alert: Do not use if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Stop use and ask a doctor

- if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting
- if sore mouth symptoms do not improve in 7 days, or irritation, pain, or redness persists or worsens

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

- 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: consult a dentist or doctor

Other information

- do not use if imprinted seal under cap is broken or missing
- 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

NDC 0283-0871-31

HURRICAIN[®]

Topical Anesthetic GEL

20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY

Manufactured for:

Beutlich[®] Pharmaceuticals, LLC

Bunnell, FL 32110

1 oz.

Drug Facts (continued)
Warnings (continued)
Sore throat warning: if sore throat is severe, persists form 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.

Do not use

- if imprinted seal under cap 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

do not exceed recommended dosage	apply to the affected area. Allow
adults and children	to remain in place at least 1 minute
2 years of age and older	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
children under 2 years of age	the product
	do not use

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

LOT: No UV
 EXP: Coating in this Area



NDC 0283-0871-31



HURRICAINÉ®
Topical Anesthetic GEL
20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY



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

1 oz.

Drug Facts

Active ingredient	Purpose
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
- 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. ▶

HURRICAINÉ TOPICAL ANESTHETIC			
benzocaine gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0871
Route of Administration	ORAL, DENTAL, PERIODONTAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g	
Inactive Ingredients			
Ingredient Name	Strength		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
Product Characteristics			
Color	brown (amber)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:0283-0871-31	1 in 1 BOX	08/15/1971
1		28.4 g in 1 BOTTLE, PLASTIC; 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	08/15/1971	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment			
Name	Address	ID/FEI	Business Operations
Speciality Pharma Manufacturing, LLC		013957125	manufacture(0283-0871)

Establishment			
Name	Address	ID/FEI	Business Operations
Dental Technologies Inc.		148312838	manufacture(0283-0871)

Revised: 10/2024

Beutlich Pharmaceuticals, LLC