

HURRICaine TOPICAL ANESTHETIC- 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.

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

HURRICaine®

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
 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

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 Coating in this Area
 EXP:

NDC 0283-0871-31

HURRICaine®
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. ▶

HURRICaine TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0871
Route of Administration	DENTAL, ORAL, 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	Marketing End 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		

1	Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/15/1971	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment

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

Establishment

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

Revised: 9/2023

Beutlich Pharmaceuticals, LLC