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 W/C Tubes

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 tube has been punctured or previously opened

- 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

NDC 0283-0871-75

HURRICAINE®

Topical Anesthetic GEL

20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY

Effective
Routinely used in dental offices

Fast-acting
Relief in 20 seconds

Tastes great!
Wild Cherry flavor

HURRICAINE®
Topical Anesthetic GEL
20% Benzocaine Oral Anesthetic

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

1 Tube – NET WT. 0.18 oz. (5.25 g)

HurriCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC,
7775 S. US Hwy 1, Suite H, Bunnell, FL 32110. www.beutlich.com
OPP 248 0518

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EXP

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Drug Facts

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Drug Facts (continued)

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WHAT YOUR DENTIST USES

NDC 0283-0871-75

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Topical Anesthetic GEL

20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY

Manufactured for:

Beutlich® Pharmaceuticals, LLC

Bunnell, FL

Made in the USA

1 Tube - NET WT. 0.18 oz. (5.25 g)

HURRICAINE 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	Marketing End Date
1	NDC:0283-0871-12	12 in 1 CELLO PACK	08/15/1971	
1	NDC:0283-0871-75	1 in 1 BOX		
1	NDC:0283-0871-01	5.25 g in 1 TUBE; Type 0: Not a 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)