

HURRICAINA 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 Unit Dose Gel and Swab - 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.

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 product film is punctured or damaged
- 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 0283-0871-45

0.5 g

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

UDGC 898 1220

HURRICAINE®
Unit-Dose Topical Anesthetic Gel
20% Benzocaine Oral Anesthetic
ORIGINAL WILD CHERRY



HurriCaine Unit Dose Gel Wild Cherry 0.5g with Swab: 0283-0871-45

60ct HurriCaine Unit Dose Gel Wild Cherry 0.5g with Swab: 0283-0871-59

Please retain Drug Facts for future reference.

Drug Facts	Purpose Benzocaine 20%.....Oral Anesthetic
Active ingredient	
Uses	For the temporary relief of occasional minor irritation and pain, associated with <ul style="list-style-type: none"> • cancer 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	Mathemoglobinemia 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: <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 Other warnings: Do not use if you have a history of allergy to local anesthetics such as procaine, butabaine, 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 if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.
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 do not use children under 2 years of age
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

Beutlich®
PHARMACEUTICALS LLC
Since 1958
7775 S. US Hwy 1, Suite H,
Bunnell, FL 32110.
www.beutlich.com

HurriCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC.
UDGC 898 1220

Manufactured for
Beutlich® Pharmaceuticals, LLC
Bunnell, FL 32110

HURRICAINE®
Unit-Dose Topical Anesthetic Gel
20% Benzocaine Oral Anesthetic
ORIGINAL WILD CHERRY

60 Unit Dose Topical Anesthetic Gel
0.017 fl. oz. (0.5 g) each

No UV Coating in this Area

LOT
EXP. DATE

7 23797 87139 1

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:0283-0871-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-0871-45	0.5 g in 1 CUP, UNIT-DOSE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/31/2021	

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
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Centrix Inc		053707303	label(0283-0871)
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Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0871) , pack(0283-0871)

Revised: 3/2023

Beutlich Pharmaceuticals, LLC