

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.

Mint Unit Dose Gel

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, butaine, benzocaine or other "caine" anesthetics.

Stop use and ask doctor if

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

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.

Adverse Reactions:

Methemoglobinemia has been reported following the use of benzocaine on extremely rare occasions. Intravenous methylene blue is the specific therapy for this condition.

Directions

- do not exceed recommend 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 ingredient

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



HurriCaine Unit Dose Gel Mint 0.5g with Swab: 0283-0998-45

HURRICAINES
Unit Dose Topical Anesthetic Gel
20% Benzocaine Oral Anesthetic
FRESH MINT

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

Manufactured by
Beutlich Pharmaceuticals, LLC
Bunnell, FL 321

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

UDS98M 901 1220

Beutlich
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Since 1934
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EP
7 23797 1 23539 1

LOT
E9-2

No LV
Cooling in this Area

Please retain Drug Facts for future reference.

Drug Facts	Purpose
Active Ingredient Benzocaine 20%	Oral Anesthetic
Uses for the temporary relief of occasional minor irritation and pain, associated with <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 	
Warnings Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that can be treated promptly because it reduces the amount of oxygen carried in the blood. The symptoms of methemoglobinemia are pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy.	
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 some mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.	

Drug Facts (continued)

Warnings (continued) Do not use if 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 do not exceed recommended dosage apply to the affected area. Allow to children 2 years remain in place at least 1 minute and of age and older then spit out. Use up to 4 times daily or as directed by a dentist or doctor. Children under 2 years of age should be supervised in the use of the 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? 1-800-238-4542 M-F: 8:00 a.m. - 4:30 p.m. ET	

HURRICAINES TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0998
Route of Administration	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	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0998-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-0998-45	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	09/15/1998	

Labeler - Beutlich Pharmaceuticals LLC (005209325)

Registrant - Beutlich Pharmaceuticals LLC (005209325)

Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies		148312838	manufacture(0283-0998)

Establishment

Name	Address	ID/FEI	Business Operations
Centrix Inc.		053707303	label(0283-0998)

Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0998) , pack(0283-0998)

Revised: 3/2023

Beutlich Pharmaceuticals LLC