

HURRICAINE TOPICAL ANESTHETIC- benzocaine gel
Beutlich Pharmaceuticals LLC

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

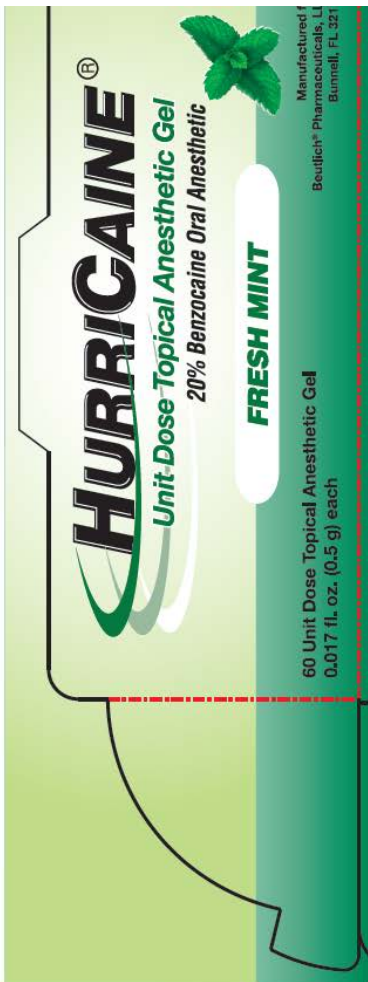
M-F: 8:00 a.m. - 4:30 p.m. ET

Principal Display Panel



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

60ct HurriCaine Unit Dose Gel Mint 0.5g with Swab: 0283-0998-59



HurrCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC.
UDS8M 901 1220

Beutlich
PHARMACEUTICALS LLC
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No UV
Coating in this Area

Please retain Drug Facts for future reference.

Drug Facts	Purpose Oral Anesthetic Benzocaine 20%
Active ingredient	
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 must be treated promptly because it reduces the amount of oxygen that can be carried in the blood. 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
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 if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.

Drug Facts (continued)	
Warnings (continued)	Do not use <ul style="list-style-type: none"> ■ 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 <ul style="list-style-type: none"> ■ adults and children 2 years 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 2 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?	1-800-258-6542 M-F: 8:00 a.m. - 4:30 p.m. ET

HURRICAINЕ 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 Drug	M022	09/15/1998	

Labeler - Beutlich Pharmaceuticals LLC (005209325)

Registrant - Beutlich Pharmaceuticals LLC (005209325)

Establishment

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

Establishment

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

Establishment

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

Revised: 10/2024

Beutlich Pharmaceuticals LLC