

HURRICAINE TOPICAL ANESTHETIC- benzocaine gel

Beutlich Pharmaceuticals, LLC

SB 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

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 product film is punctured or damaged
- for teething
- in children under 2 years of age

When using this product

When using this product avoid contact with eyes

Keep out of reach of children.

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**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

Principle Display Panel

NDC 0283-1016-45

0.5 g

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

UDSG 836 1220

HURRICAINÉ®
Unit Dose Topical Anesthetic Gel
20% Benzocaine Oral Anesthetic
STRAWBERRY



Do not use if product film is punctured or damaged.

HurriCaine Unit Dose Gel Strawberry 0.5g with Swab: 0283-1016-45

60ct HurriCaine Unit Dose Gel Strawberry 0.5g with Swab: 0283-1016-59

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 canker sores, sore throat and throat irritation, or after 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.	
Some 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 worsens, see your dentist or doctor promptly.	

Drug Facts (continued)
Warnings (continued) Do not use • if product film is punctured or damaged • for washing • in children under 2 years of age • for bathing • 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 area to be anesthetized • children 2 years of age and older: apply in film at least 1 minute and of age and older: then spit out. Use up to 4 times daily or 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

7 23797 01659 6

LOT No UV
Exp. Dating in this Area

Beutlich®
PHARMACEUTICALS LLC
Since 1934
7775 S. US Hwy 1, Suite H,
Bunnell, FL 32110,
www.beutlich.com

HurriCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC.
UDSGS 836 1220

HURRICAINÉ TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-1016
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
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 3500 (UNII: FVS1AZD90Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	yellow (colorless to pale yellow)	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-1016-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-1016-45	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	10/15/2016	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)**Registrant** - Beutlich Pharmaceuticals, LLC (005209325)**Establishment**

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-1016) , pack(0283-1016)

Establishment

Name	Address	ID/FEI	Business Operations
Centrix Inc.		053707303	label(0283-1016)

Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies		148312838	manufacture(0283-1016)

Revised: 10/2024

Beutlich Pharmaceuticals, LLC