

HURRICAINE TOPICAL ANESTHETIC GEL- benzocaine gel
Beutlich Pharmaceuticals, LLC

WM 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 imprinted seal under cap is broken or missing
- 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 ingredient

flavor, polyethylene glycol, sodium saccharin

Questions or comments?

1-800-238-8542

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

Principal Display Panel

NDC 0283-0293-45

0.5 g

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

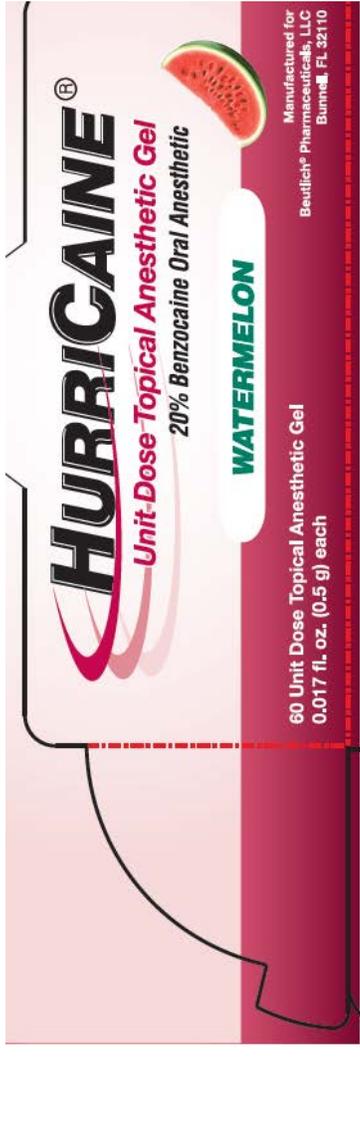
UD38W 920 1220

HURRICAINÉ[®]
Unit Dose Topical Anesthetic Gel
20% Benzocaine Oral Anesthetic
WATERMELON



HurriCaine Unit Dose Gel Watermelon 0.5g with Swab: 0283-0293-45

60ct HurriCaine Unit Dose Gel Watermelon 0.5g with Swab: 0283-0293-59



HURRICAINÉ[®]
Unit Dose Topical Anesthetic Gel
20% Benzocaine Oral Anesthetic
WATERMELON

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

Manufactured for:
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Bunnell, FL 32110

UD38W 920 1220

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

Beutlich
PHARMACEUTICALS, LLC
Since 1954
7775 S. US Hwy 1, Suite H,
Bunnell, FL 32110,
www.beutlich.com

LOT: No UV
EXP: Coating in this Area

FPO 23797 29359

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 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. Do not use if you have a history of allergy to local anesthetics such as procaine, tetracaine, benzocaine, or other "caine" anesthetics. <ul style="list-style-type: none"> ■ rash, fever, or blue-colored skin (cyanosis) ■ headache ■ rapid heart rate ■ shortness of breath ■ dizziness or lightheadedness ■ fatigue or lack of energy 	
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 relief, or if you have a history of allergy to local anesthetics, contact your doctor or Poison Control Center immediately.	Directions do not exceed recommended dosage adults and children 2 years and older: apply to the affected area. Allow to remain in place at least 1 minute and or apply and older: 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? 1-800-238-8542 M-F: 8:00 a.m. - 4:30 p.m. ET	

HURRICAINÉ TOPICAL ANESTHETIC GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0293
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	white (colorless)	Score	
Shape		Size	
Flavor	WATERMELON	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0293-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-0293-45	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	02/15/1993	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Establishment			
Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0293) , pack(0283-0293)

Establishment			
Name	Address	ID/FEI	Business Operations
Centrix Inc		053707303	label(0283-0293)

Establishment			
Name	Address	ID/FEI	Business Operations
Dental Technologies Inc.		148312838	manufacture(0283-0293)

