HURRICAINE TOPICAL ANESTHETIC- benzocaine gel Beutlich Pharmaceuticals, LLC

HurriCaine Gel Syringe 1.2g - Pina Colada

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

- for teething
- in children under 2 years of age
- if the tray seal is broken or missing
- if the syringe cap is broken or missing

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

Storage and Handling

store at 20°-25°C (68°-77°F)

Inactive ingredients

flavor, polyethylene glycol, sodium saccharin

Questions or comments?

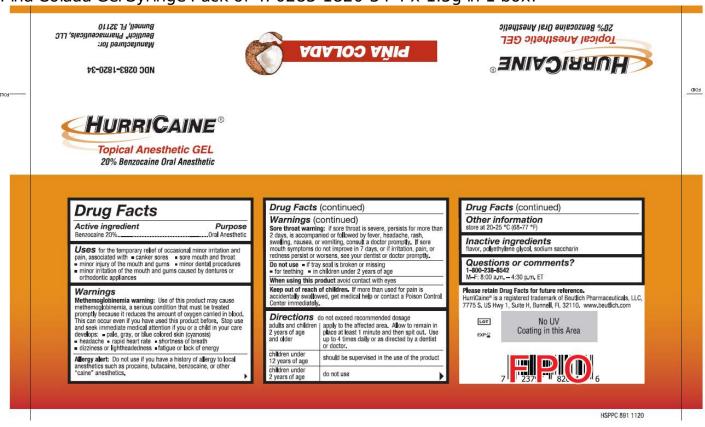
1-800-238-8542

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

Principal Display Panel



Pina Colada Gel Syringe Pack of 4: 0283-1820-34 4 x 1.5g in 1 box.



HURRICAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-1820
Route of Administration	DENTAL, PERIODONTAL, ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOCAINE (UNII: U3RSY48IW5) (BENZOCAINE - UNII:U3RSY48IW5)	BENZ OCAINE	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	yellow (yellow to pale orange)	Score	
Shape		Size	
Flavor	COCONUT (Pina Colada Flavor)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283- 1820-34	4 in 1 TRAY	07/01/2023	03/31/2026
1	NDC:0283- 1820-43	1.5 g in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M022	02/28/2021		

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Revised: 7/2023 Beutlich Pharmaceuticals, LLC