HURRICAINE TOPICAL ANESTHETIC- benzocaine gel Beutlich Pharmaceuticals, LLC

HurriCaine Gel LV Syringe - Mint

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 the tray seal is broken or missing
- if cap is missing 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

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

• store at 20°-25° C (68°-77° F)

Inactive ingredients

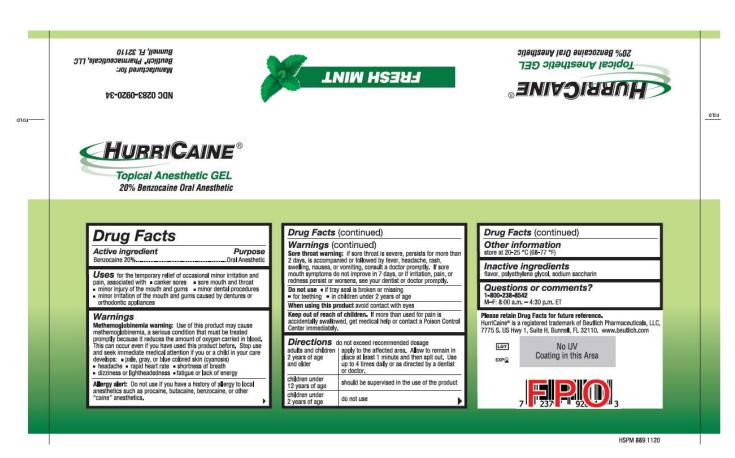
• flavor, polyethylene glycol, sodium saccharin

Questions or comments?

1-800-238-8542

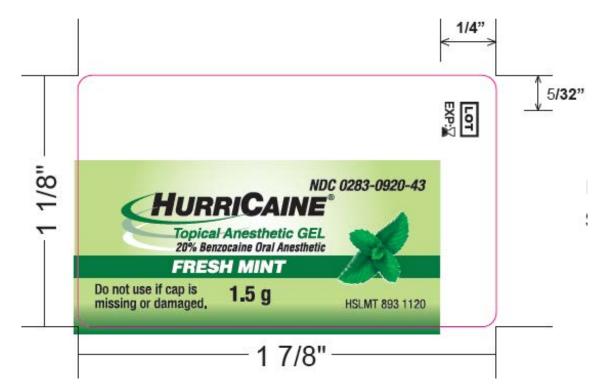
M-F: 8:00 a.m. - 4:30 p.m. ET

Principal Display Panel



Gel Syringe Unit: 0283-1820-43 1.5g in 1 syringe

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



HURRICAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

l	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0920
ı	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		Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

F	Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0283- 0920-34	4 in 1 BOX	01/31/2021	04/30/2026	
1	NDC:0283- 0920-43	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	01/31/2021		

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dental Technologies, Inc.		148312838	manufacture(0283-0920)	

Revised: 11/2023 Beutlich Pharmaceuticals, LLC