HURRICAINE TOPICAL ANESTHETIC- benzocaine gel Beutlich Pharmaceuticals, LLC

HurriCaine Gel LV Syringe - Wild Cherry

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
- 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

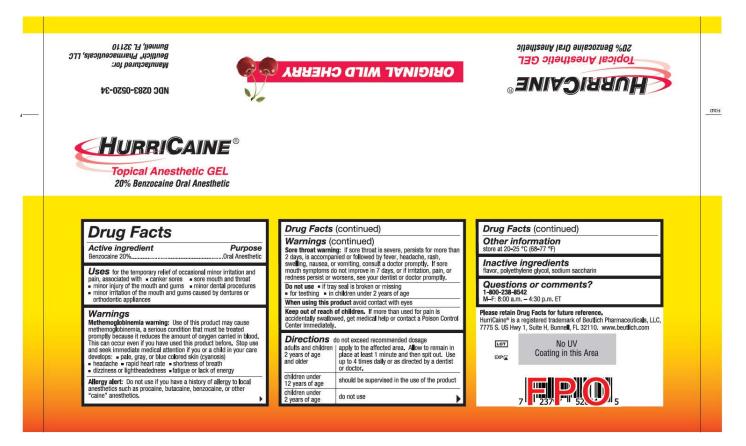
• flavor, polyethylene glycol, sodium saccharin

Questions or comments?

1-800-238-8542

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

Principal Display Panel



Gel Syringe Unit: 0283-0520-43 1.5g in 1 syringe

Gel Syringe Pack of 4: 0283-0520-34 4 x 1.5g in 1 box.

HURRICAINE TO	PICAL ANESTHETIC			
oenzocaine gel				
Product Informatio	n			
Product Type	HUMAN OTC DRUG	lter	n Code (Source)	NDC:0283-0520
Route of Administratio	ORAL, DENTAL, PERIODONTAL			
Active Ingredient/Active Ingredient/Active	ctive Mojety			
	h Strength			
	ngredient Name 48JW5) (BENZOCAINE - UNII:U3RSY48JW5	5)	Basis of Strengt	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 Characteris	stics			

	nape			Si	ze			
Flavor			CHERRY	Im	nprint Code			
Co	ontains							
Pa	ackaging							
#	ltem Code		Package Desc	Package Description			Marketing Start Date	
	NDC:0283- 0520-34	4 in 1 E	30X				01/31/2021	
	NDC:0283- 0520-43		5 g in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)					
Μ	larketin	g In	formation					
Marketing Ap Category			Application Number or Citation	^r Monograph	Marketing Start Date		Marketing End Date	
OTC Monograph Drug M022		n 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(0283-0520)				

Revised: 11/2023

Beutlich Pharmaceuticals, LLC