HURRICAINE TOPICAL ANESTHETIC LIQUID- benzocaine liquid Beutlich Pharmaceuticals, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

W/C Liquid

Active ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

for 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

store at 20°-25°C (68°-77°F)

Inactive ingredients

flavor, polyethylene glycol, sodium saccharin

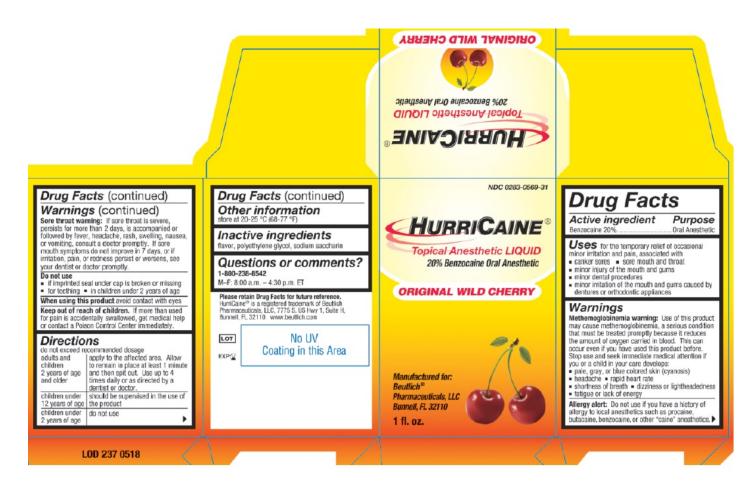
Questions or comments?

1-800-238-8542

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

Principal Display Panel

NDC 0283-0569-31



HURRICAINE®

Topical Anesthetic LIQUID

20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY

Manufactured for:

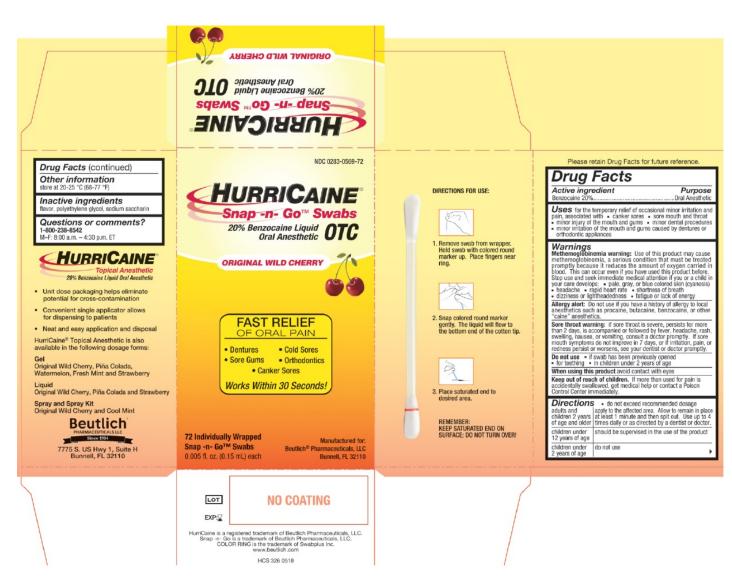
Beutlich® Pharmaceuticals, LLC

Bunnell, FL 32110

Made in the USA

1 fl. oz.

NDC: 0283-0569-72



NDC: 0283-0569-02



URRICAINE

Please retain Drug Facts for future reference

Drug Facts

Active ingredient Purpose Benzocaine 20%......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

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Drug Facts (continued)

Warnings (continued) Do not use

- if swab has been previously opened
- for teething
 in children under 2 years of age

When using this product avoid contact with eves

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

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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

NDC 0283-0569-02

HURRICAINE

Snap -n- Go™ Swabs 20% Benzocaine Liquid OTC
Oral Anesthetic

ORIGINAL WILD CHERRY



FAST RELIEF OF ORAL PAIN

- Dentures
- · Cold Sores
- Sore Gums
- Orthodontics
- · Canker Sores

Works Within 30 Seconds!

2 Individually Wrapped Snap -n- Go™ Swabs

0.005 fl. oz. (0.15 mL) each

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

DIRECTIONS FOR USE:



 Remove swab from wrapper. Hold swab with colored round marker up. Place fingers near ring.



2. Snap colored round marker gently. The liquid will flow to the bottom end of the cotton tip.



3. Place saturated end to desired area. REMEMBER: KEEP SATURATED END ON SURFACE; DO NOT TURN OVER!



7775 S. US Hwy 1, Suite H Bunnell, FL 32110

LOT EXP:☑

NO COATING

HurriCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC. Snap -n- Go is a trademark of Beutlich Pharmaceuticals, LLC. COLOR RING is the trademark of Swabplus Inc. www.beutlich.com HSG2 703 0518

HURRICAINE TOPICAL ANESTHETIC LIQUID

benzocaine liquid

Product Information

NDC:0283-0569 HUMAN OTC DRUG Item Code (Source) **Product Type**

Route of Administration DENTAL, PERIODONTAL, ORAL

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)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

F	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0283- 0569-31	29.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/1969		
2	NDC:0283- 0569-17	1 g in 1 PACKET; Type 0: Not a Combination Product	01/28/2020		
3	NDC:0283- 0569-72	72 g in 1 APPLICATOR; Type 0: Not a Combination Product	05/15/1969		
4	NDC:0283- 0569-02	2 g in 1 APPLICATOR; Type 0: Not a Combination Product	05/15/1969		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/15/1969	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment			
Name	Address	ID/FEI	Business Operations
Dental Technologies Inc.		148312838	manufacture(0283-0569)

Establishment			
Name	Address	ID/FEI	Business Operations

Speciality Pharma Manufacturing	013957125	manufacture(0283-0569)
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Establishme	nt		
Name	Address	ID/FEI	Business Operations
SWABPLUS		116984439	manufacture(0283-0569)

Establishment			
Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-0569), pack(0283-0569)

Revised: 3/2023 Beutlich Pharmaceuticals, LLC