

HURRICAINA 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



HURRICAINÉ®

Topical Anesthetic LIQUID

20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY

Manufactured for:

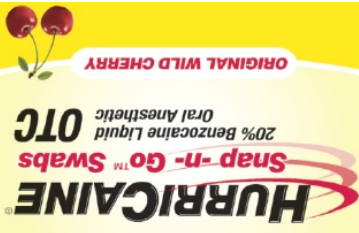
Beutlich® Pharmaceuticals, LLC

Bunnell, FL 32110

Made in the USA

1 fl. oz.

NDC: 0283-0569-72



NDC 0283-0569-72

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



FAST RELIEF OF ORAL PAIN

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

Works Within 30 Seconds!

72 Individually Wrapped Snap-n-Go™ Swabs
 0.005 fl. oz. (0.15 mL) each

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

Drug Facts (continued)

Other information
 store at 20-25 °C (68-77 °F)

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 flavor, polyethylene glycol, sodium saccharin

Questions or comments?
 1-800-238-8542
 M-F: 8:00 a.m. – 4:30 p.m. ET



- Unit dose packaging helps eliminate potential for cross-contamination
- Convenient single applicator allows for dispensing to patients
- Neat and easy application and disposal

HurriCaine® Topical Anesthetic is also available in the following dosage forms:

Gel
 Original Wild Cherry, Piña Colada, Watermelon, Fresh Mint and Strawberry

Liquid
 Original Wild Cherry, Piña Colada and Strawberry

Spray and Spray Kit
 Original Wild Cherry and Cool Mint

Beutlich
 PHARMACEUTICALS, LLC
 Since 1951
 7775 S. US Hwy 1, Suite H
 Bunnell, FL 32110

DIRECTIONS FOR USE:

1. 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!

Please retain Drug Facts for future reference.

Drug Facts

| Active ingredient | Purpose |
|-------------------|-----------------|
| Benzocaine 20% | Oral Anesthetic |

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Do not use • if swab has been previously opened • for teething • in children under 2 years of age

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| Directions | • do not exceed recommended dosage |
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| children under 2 years of age | do not use |

LOT [] **NO COATING**

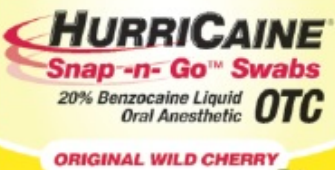
HurriCaine is a registered trademark of Beutlich Pharmaceuticals, LLC.
 Snap-n-Go is a trademark of Beutlich Pharmaceuticals, LLC.
 COLOR RING is the trademark of Swabplus Inc.
 www.beutlich.com

HCS 326 0518

NDC: 0283-0569-02



NDC 0283-0569-02



FAST RELIEF OF ORAL PAIN

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

Works Within 30 Seconds!

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

Beutlich
PHARMACEUTICALS LLC
Since 1954

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

Please retain Drug Facts for future reference.

Drug Facts

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Drug Facts (continued)

Warnings (continued)

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LOT
EXP

NO COATING

Hurricane® 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



HURRICANE TOPICAL ANESTHETIC LIQUID

benzocaine liquid

Product Information

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

Packaging

| # | 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) |

| Establishment | | | |
|----------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| SWABPLUS | | 116984439 | manufacture(0283-0569) |

Revised: 1/2020

Beutlich Pharmaceuticals, LLC