

HURRICAINA TOPICAL ANESTHETIC- benzocaine gel
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.

HurriCaine Gel Watermelon 1.5oz tube

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 tube has been punctured or previously opened
- 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

NDC 0283-0220-27

HURRICAINE®

Topical Anesthetic GEL
20% Benzocaine Oral Anesthetic

WATERMELON

NET WT. 1.5 oz. (42.52g)

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



Do not use if tube has been punctured or previously opened. Please refer to Drug Facts for product uses and directions.
HurriCaine® is a registered trademark of Beutlich Pharmaceuticals, LLC,
7775 S. US Hwy 1, Suite H, Bunnell, FL 32110.
www.beutlich.com
GWT 925 0822



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

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HURRICAINE®

Topical Anesthetic GEL

20% Benzocaine Oral Anesthetic

WATERMELON

Manufactured for:
Beutlich® Pharmaceuticals, LLC

Bunnell, FL

Made in the USA

1 Tube - NET WT. 1.5 oz. (42.52 g)

HURRICAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0283-0220 |
|---------------------|----------------|---------------------------|---------------|

Route of Administration DENTAL, ORAL, 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 | WATERMELON | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0283-0220-27 | 42.52 g in 1 TUBE; Type 0: Not a Combination Product | 08/31/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 08/31/2023 | |

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Dental Technologies, Inc. | | 148312838 | manufacture(0283-0220) |