

HURRICAINA TOPICAL ANESTHETIC- benzocaine spray
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 Cool Mint Spray

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.

Flammable. Do not use near fire or flame. Avoid smoking during use.

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

- for teething
- in children under 2 years of age

When using this product

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- avoid spraying in eyes
- do not store at temperature above 49 °C (120 °F)
- do not puncture or incinerate. Contents under pressure.
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

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
- firmly insert extension tube into spray can valve and ensure it fits securely into the actuator opening
- position the extension tube 1-2 inches from the affected area
- spray 1/2 second (press and immediately release actuator)
- repeat once if necessary
- anesthesia is accomplished in approximately 20 seconds

adults and children 2 years of age and older: 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

Inactive ingredients

flavor, hydrocarbon propellant (isobutane and propane), 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

Cool Mint Spray NDC 0283-0914-02

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

Gel – 1 oz. bottle, 1.5 oz. gel tube and unit dose

- Original Wild Cherry
- Watermelon
- Piña Colada
- Fresh Mint
- Strawberry

Prefilled Syringes

- Original Wild Cherry
- Piña Colada
- Fresh Mint
- Strawberry

Liquid – 1fl. oz. bottle

- Original Wild Cherry
- Piña Colada

Snap -n- Go™ Swabs – Box of 72 swabs

- Original Wild Cherry

Spray – 2 oz. Spray and 1 disposable extension tube (for single patient use)*

- Cool Mint
- Original Wild Cherry

Spray Kit – for multiple patient use*

- Cool Mint
 - 2 oz. spray and 100 individually sealed disposable extension tubes
- Original Wild Cherry
 - 2 oz. spray and 200 disposable extension tubes

*Additional extension tubes are available for purchase.

- Green individually sealed disposable extension tubes – Box of 100
- Red disposable extension tubes – Box of 200

HurriCaine ONE® Unit Dose Non-Aerosol Spray

Boxes of 2 each or 25 each

- Original Wild Cherry

HurriCaine and HurriCaine ONE are registered trademarks of Beutlich® Pharmaceuticals, LLC. Snap -n- Go is a trademark of Beutlich Pharmaceuticals, LLC.



Drug Facts

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Drug Facts (continued)

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Manufactured for:

Beutlich®
PHARMACEUTICALS LLC
Since 1954

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

Drug Facts (continued)

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Please retain Drug Facts for future reference.



COOL MINT

Topical Anesthetic SPRAY KIT
 20% Benzocaine Oral Anesthetic

HURRICAINE

NDC 0283-0914-60

HURRICAINE[®]
 Topical Anesthetic SPRAY KIT
 20% Benzocaine Oral Anesthetic

COOL MINT

Manufactured for:

Beutlich[®]
 PHARMACEUTICALS LLC

Since 1954

Contents:
 1 HurriCaine[®] Topical Anesthetic Spray – 2 oz. (57 g)
 100 Individually Sealed Disposable Extension Tubes

HurriCaine is a registered trademark of Beutlich[®] Pharmaceuticals, LLC,
 7775 S. US Hwy 1, Suite H, Dunedin, FL 32110.
 www.beutlich.com HSKM 778 0518

LOT

EXP

HURRICAINE TOPICAL ANESTHETIC

benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0914
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)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MINT (UNII: FV98Z8GITP)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0914-02	59.7 g in 1 CAN; Type 0: Not a Combination Product	09/01/2014	
2	NDC:0283-0914-60	1 in 1 BOX	09/01/2014	
2	NDC:0283-0914-02	59.7 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/01/2014	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	pack(0283-0914)

Establishment

Name	Address	ID/FEI	Business Operations
TRI-PAC INC.		020844956	manufacture(0283-0914)