

HURRICAINES- topical anesthetic 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 One
Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

Uses for the temporary relief of occasional minor irritation and pain associated with sore mouth and throat

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 foil pouch has been 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

- do not exceed recommended dosage

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

Other information

- store at 15-30 °C (59-86 °F)

Inactive ingredients

flavor, polyethylene glycol, sodium saccharin

Questions or comments?

1-800-238-4582

☐M-F: 8:00 a.m. - 4:30 p.m. ET

Principal Display Panel

HurriCaine One 2ct carton



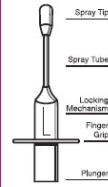
HURRICANE ONE®

Unit Dose Non-Aerosol Spray
20% Benzocaine Oral Anesthetic
ORIGINAL WILD CHERRY FLAVOR

Beutlich
PHARMACEUTICALS, LLC
Since 1954

Manufactured for
Beutlich® Pharmaceuticals, LLC
Bunnell, FL 32110

PRODUCT DIAGRAM



2 Unit Dose Non-Aerosol Sprays - 0.017 fl. oz. (0.5 mL) each

Please retain Drug Facts for future reference

Drug Facts	
Active ingredient Benzocaine 20%	Purpose Oral Anesthetic
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Drug Facts (continued)	
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Questions or comments? 1-800-238-8542 M-F: 8:00 a.m. - 4:30 p.m. ET	

HO2B 595 0518



www.beutlich.com
Beutlich Pharmaceuticals, LLC
7775 S. US Hwy 1, Suite H, Bunnell, FL 32110
Hurricane ONE is a trademark of Beutlich Pharmaceuticals, LLC.

Principal Display Panel



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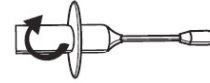
DIRECTIONS



Tear at notch to open pouch. Remove HurriCaine ONE® from pouch.



To unlock, turn clockwise.



Grasp HurriCaine ONE firmly by placing your first and second fingers on the finger grip, while your thumb is touching the base of the plunger.



Position patient with mouth open. Aim spray tip toward the back of patient's throat.



Apply firm pressure to plunger by pushing thumb forward to initiate spray action. Instruct patient to swallow 1-2 times. Anesthesia is accomplished within 30 seconds and lasts approximately 15 minutes.

HurriCaine One 25ct carton

HURRICAINE

topical anesthetic spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0610
Route of Administration	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)	349 mg in 1 g
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	12 mg in 1 g
CHERRY (UNII: BUC5I9595W)	439 mg in 1 g

Product Characteristics

Color		Score	
Shape		Size	

Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0610-11	2 in 1 BOX	04/01/2016	
1	NDC:0283-0610-43	0.492 g in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:0283-0610-26	25 in 1 BOX	04/01/2016	
2	NDC:0283-0610-43	0.492 g in 1 APPLICATOR; 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	06/15/2010		

Labeler - Beutlich Pharmaceuticals LLC (005209325)

Registrant - Beutlich Pharmaceuticals LLC (005209325)

Establishment			
Name	Address	ID/FEI	Business Operations
SPECIALITY PHARMA MANUFACTURING, LLC		013957125	manufacture(0283-0610)

Revised: 8/2019

Beutlich Pharmaceuticals LLC