

HURRICAINA TOPICAL ANESTHETIC- benzocaine gel
Beutlich Pharmaceuticals LLC

Mint Gel 1oz

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

Allergy alert: Do not use if you have a history of allergy to local anesthetics such as procaine, butaine, benzocaine or other "caine" anesthetics.

Stop use and ask doctor if

- sore throat is severe, persists for more than 2 days, is accompanied or followed by a fever, headache, rash, swelling, nausea or vomiting
- sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens

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.

Adverse Reactions:

Methemoglobinemia has been reported following the use of benzocaine on extremely rare occasions. Intravenous methylene blue is the specific therapy for this condition.

Directions

- do not exceed recommend 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: consult a dentist or doctor

Other information

- do not use if imprinted seal under cap is broken or missing
- store at 20-25 °C (68-77 °F)

Inactive ingredient

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 0283-0998-31

HURRICAINÉ®

Topical Anesthetic GEL

20% Benzocaine Oral Anesthetic

FRESH MINT

Manufactured for:

Beutlich®

Pharmaceuticals, LLC

Bunnell, FL

www.beutlich.com

HURRICAINÉ TOPICAL ANESTHETIC			
benzocaine gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0283-0998
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)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0998-31	28.4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/1998	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/15/1998	

Labeler - Beutlich Pharmaceuticals LLC (005209325)

Registrant - Beutlich Pharmaceuticals LLC (005209325)

Establishment			
Name	Address	ID/FEI	Business Operations
Dental Technologies		148312838	manufacture(0283-0998)

Establishment			
Name	Address	ID/FEI	Business Operations
Speciality Pharma Manufacturing		013957125	manufacture(0283-0998)