

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.

Mint Gel

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

HURRICAINA 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	
2	NDC:0283-0998-43	1 g in 1 PACKET; Type 0: Not a Combination Product	01/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	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		0 13957125	manufacture(0283-0998)

Revised: 1/2020

Beutlich Pharmaceuticals LLC