HURRICAINE 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.

SB Unit Dose 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

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 product film is punctured or damaged
• for teething
• in children under 2 years of age

When using this product

When using this product avoid contact with eyes

Keep out of reach of children.

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

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

Principle Display Panel

HurriCaine Unit Dose Gel Strawberry 0.5g with Swab: 0283-1016-45

60ct HurriCaine Unit Dose Gel Strawberry 0.5g with Swab: 0283-1016-59

HURRICAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0283-1016
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)	
POLYETHYLENE GLYCOL 3500 (UNII: FVS1AZD90Y)	

Product Characteristics

Color	yellow (colorless to pale yellow)	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-1016-59	60 in 1 BOX	01/31/2021	
1	NDC:0283-1016-45	0.5 g in 1 CUP, UNIT-DOSE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/15/2016	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment

Name	Address	ID/FEI	Business Operations
Dental Technologies		148312838	manufacture(0283-1016)

Establishment

Name	Address	ID/FEI	Business Operations
Centrix Inc.		053707303	label(0283-1016)

Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-1016) , pack(0283-1016)

Revised: 3/2023 Beutlich Pharmaceuticals, LLC