ULTRACARE ANESTHETIC GEL- benzocaine gel
The Belport Company, Inc. DBA Gingi-Pak

UltraCare, Bubblegum

Uses

Uses Reduce pain or discomfort caused by • minor dental procedures • minor gum injury • canker sores • sore throat • minor mouth or gum irritations caused by dentures or orthodontic appliances

Directions

Indications Anesthesia of mucous membranes of oropharynx. Minimizes the pain of ulcers, needle puncture, deep scaling procedures, and the application of matrix bands. Also an aid in the taking of impressions or intraoral radiographs of patients with an excessive gag reflex.

Reduce pain or discomfort caused by minor dental procedures • minor gum injury • canker sores • sore throat • minor mouth or gum irritations caused by dentures or orthodontic appliances.

Allergy alert Do not use if you have history of allergy to any "caine" local anesthetics or FD&C Red #40. Avoid contact with eyes.

Active ingredient **Purpose**
Benzocaine 20% w/v ..... Oral Anesthetic

Keep out of reach of children.

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Do not use in patients with history of hypersensitivity to any ester-type local anesthetics. Do not use the product for teething or in infants and children younger than 2 years.

DO NOT USE IF TAMPER-EVIDENT SLEEVE IS BROKEN.

Ask a doctor (pharmacist) before use if you have severely traumatized, infected mucosal areas or areas of the posterior pharynx that might obtund protective reflexes. **Stop use and ask a doctor if** • Sore throat is severe and more than 2 days • Fever, headache, rash, nausea, or vomiting develops • Mouth sore does not go away within 10 days • Irritation, pain, or redness worsens.

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Dosage & Administration Mucosa should be dried prior to application. Removal of excess saliva with cotton rolls or saliva ejectors will minimize dilution of the local anesthetic. Sterile cotton or gauze should be used in applying anesthetic to mucosa. Care must be taken to avoid cross-contamination between patients. Total dose should not exceed the amount required for anesthesia. • Apply to the affected area. • Remain in place for at least 1 minute and then spit. • Use up to 4 times daily or as directed by a dentist or doctor. • Do not exceed recommended dosage. • This product is for adults and children 2 years of age and older. • Children under 2 years of age should consult a dentist or a doctor.

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Inactive Ingredients Polyethylene Glycol 400 (PEG 400) NF, Polyethylene Glycol 3350 (3550) NF, Sodium Saccharin, artificial flavor, FD&C Red #40.

The inactive ingredients in UltraCare bubblegum are polyethylene glycol 400 (PEG 400) NF, Polyethylene Glycol 3350 (3350) NF, Sodium Saccharin, artificial Flavor, FD$C Red #40.

Warnings

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For external use only

Allergy alert Do not use if you have history of allergy to any "caine" local anesthetics or FD&C Red #40. Avoid contact with eyes. **Keep out of reach of children.**

Warnings (Continued)

If more than normal usage amount is accidentally swallowed, get medical help or contact a Poison Control Center immediately. Do not exceed recommended dosage.

Methemoglobinemia warning

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Cease use and seek immediate medical attention if one of the following symptoms develops: • Pale, gray, or blue colored skin (cyanosis) • Headache • Rapid heart rate • Shortness of breath • Dizziness or lightheadedness • Fatigue or lack of energy

Storage Avoid excessive heat above 40° C (104° F). Net content 1 oz. (30 g).

Oral Anesthetic

Drug Facts

Active ingredient **Purpose**
Benzocaine 20% w/v ..... Oral Anesthetic

Uses Reduce pain or discomfort caused by • minor dental procedures • minor gum injury • canker sores • sore throat • minor mouth or gum irritations caused by dentures or orthodontic appliances

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Other information

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Questions or comments?

800.552.5512 or ultradent.com

◂ OPEN HERE

Made in USA
NDC 10129-072-01
Manufactured for
Ultradent Products Inc.
505 West Ultradent Drive
South Jordan, UT 84095, USA

1012309AR01 112723

ULTRA CARE™
TOPICAL ANESTHETIC GEL

20%
Benzocaine Oral Anesthetic
1 oz. (30 g)

Bubble Gum

REF 302

ultradent.com
800.552.5512

ULTRACARE ANESTHETIC GEL

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10129-072
Route of Administration	DENTAL, PERIODONTAL, TOPICAL		

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 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-072-01	30 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/20/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	03/20/2024	

Labeler - The Belport Company, Inc. DBA Gingi-Pak (008480121)

Revised: 3/2024

The Belport Company, Inc. DBA Gingi-Pak