

ULTRACARE ANESTHETIC GEL- benzocaine gel
The Bellport Company, Inc. dba Gingi-Pak

UltraCare

Active Ingredient

Benzocaine 20% w/v

Warnings

For external use only.

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

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.

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

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 you have history of allergy to any "caine" local anesthetics.

Avoid contact with eyes.

Keep out of reach of children.

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

Purpose

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

Indications

Anesthesia of mucous membrane 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 reflexes.

Dosage and 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.

Other information

Inactive Ingredients

Polyethylene Glycol 400 (PEG 400) NF, Polyethylene Glycol 3350 (3550) NF, Sodium Saccharin, natural and artificial flavors.

Storage

Avoid excessive heat above 40C (104F).

Net content 1oz. (30 grams)



ULTRACARE ANESTHETIC GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-071
Route of Administration	DENTAL, TOPICAL, 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)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (walterberry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-071-01	30 g in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	02/08/2023	

Labeler - The Bellport Company, Inc. dba Gingi-Pak (008480121)

Registrant - Jeff Nichols (008480121)

Establishment

Name	Address	ID/FEI	Business Operations
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The Bellport Company, Inc. dba Gingi-Pak		008480121	manufacture(10129-071)
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Revised: 1/2025

The Bellport Company, Inc. dba Gingi-Pak