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

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.

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 applicances

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 amout required for anethesia.

- 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 adultsand children 2 years of age and older.
- Chidlren 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 final	M022	02/08/2023	

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

Registrant - Jeff Nichols (008480121)

Establishment

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

Revised: 2/2023 The Bellport Company, Inc. dba Gingi-Pak