

**GINGICAIN GEL, COTTON CANDY FLAVOR- gingicaine gel, cotton candy flavor gel**

**Gingi-Pak a Division of the Belport**

*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.*

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**GingiCaine Gel, Cotton Candy**

**Active ingredients**

<b>Active ingredient</b>	<b>Purpose</b>
Benzocaine 20% w/v .....	Oral Anesthetic

**Inactive Ingredients**

Polyethylene Glycol 3350

Polyethylene Glycol 400

Potassium Sodium Saccharate

## **Precautions**

**Precautions** Dentists should avoid application to severely traumatized mucosal areas which are infected or areas of the posterior pharynx that might obtund protective reflexes. Local anesthetics should be used with caution in patients with known drug sensitivities, particularly those known to be allergic to ester-type anesthetics (procaine, benzocaine, tetracaine). Dentists should avoid contact with all local anesthetics to avoid possible sensitization.

### **Consult a doctor**

**Consult a doctor promptly** if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting • if mouth sore does not go away within 10 days • if irritation, pain, or redness persists or worsens. Avoid contact with eyes. Keep out of reach of children. If more than normal usage amount is accidentally swallowed, get medical help or contact a Poison Control Center immediately. Do not exceed recommended dosage.

### **Allergy Alert and Contraindications**

**Allergy alert** Do not use if you have history of allergy to any “caine” local anesthetics or FD&C Red #40.

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

### **Purpose**

Gingicaine Gel is a topical anesthetic used by Dentists just prior to an injection. Gingicaine is usually spread on a patients gum.

**Keep out of reach of children**

All Gingicaine Gel products should be kept out of reach of children. Call a doctor immediately if Gingicaine is ingested or swallowed by a child and follow directions accordingly.

## **Dosage and Adminnstration**

**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 split out. • 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.

## Indications and Uses

**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.

**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

## Avoid excessive heat

**Avoid Excessive heat** Above 40 °C (104 °F).

## Warnings

**Warnings** For external use only. 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 children under 2 years of age.**

## GingiCaine Gel, Cotton Candy Label

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<b>Active ingredient</b> Benzocaine 20% w/v.	<b>Warnings</b> (continued) 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 children under 2 years of age.	<b>Directions</b> (continued)
<b>Purpose</b> Oral Anesthetic	<b>Directions</b> 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.	<b>Dosage &amp; Administration</b> 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 split out. • 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.
<b>Uses</b> 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.	<b>Contraindications</b> should not be used in patients with history of hypersensitivity to ester-type local anesthetics. Do not use the product for soothing or in infants and children younger than 2 years.	<b>Caution Avoid Excessive heat</b> Above 40 °C (104 °F). <b>Net content</b> 1 oz. (30 grams).
<b>Caution Avoid Excessive heat</b> Above 40 °C (104 °F). <b>Net content</b> 1 oz. (30 grams).	<b>Precautions</b> Dentists should avoid application to severely traumatized mucosal areas which are infected or areas of the posterior pharynx that might elicit protective reflexes. Local anesthetics should be used with caution in patients with known drug sensitivities, particularly those known to be allergic to	
<b>DO NOT USE IF TAMPER-EVIDENT SLEEVE IS BROKEN.</b>		
<b>Warning:</b> For external use only. 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		



**GINGICAINE GEL, COTTON CANDY FLAVOR**  
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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10129-037
<b>Route of Administration</b>	DENTAL, ORAL, PERIODONTAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	260 mg
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	520 mg
<b>POTASSIUM SODIUM SACCHARATE</b> (UNII: 73U34YC90U)	20 mg

**Product Characteristics**

<b>Color</b>	pink (Cotton candy flavor)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10129-037-01	1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/1993	
2	NDC:10129-037-05	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/1999	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	03/26/1993	

**Labeler** - Gingi-Pak a Division of the Belport (008480121)