

GINGICAIN GEL- gingicaine gel banana 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.

GingiCaine Gel, Banana

Active ingredient

Active ingredient	Purpose
Benzocaine 20% w/v	Oral Anesthetic

Inactive ingredient

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 promptly

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 Contraindication

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.

Allergy alert Do not use if you have history of allergy to any "caine" local anesthetics.

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 Administration

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 Banana label

<p>Drug Facts</p> <p>Active ingredient Benzocaine 20% w/v</p> <p>Purpose Oral Anesthetic</p> <p>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.</p> <p>Allergy alert Do not use if you have history of allergy to any "caine" local anesthetics.</p> <p>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.</p> <p>DO NOT USE IF TAMPER-EVIDENT SLEEVE IS BROKEN.</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>Warnings (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.</p> <p>Directions</p> <p>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.</p> <p>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.</p> <p>Caution Avoid Excessive heat Above 40 °C (104 °F). Net content 1 oz. (30 grams).</p> <p>Precautions Dentists should avoid application to severely traumatized mucosal areas which are irritated 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</p>	<p>Drug Facts (continued)</p> <p>Directions (continued)</p> <p>ester-type anesthetics (procaine, benzocaine, tetracaine). Dentists should avoid contact with all local anesthetics to avoid possible sensitization.</p> <p>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.</p> <p>#08L8L20113 Rev. AD</p>	<p style="text-align: right;">◀ OPEN HERE</p> <p style="text-align: center;">GingiCaine®</p> <p style="text-align: center;"><i>Topical Anesthetic Gel</i></p> <p>20% Benzocaine Oral Anesthetic</p> <p>REF 20113 NDC 10129-035-03</p>  <p>Manufactured by Gingi-Pak 4525 Calle Alto Camarillo, CA 93012 USA www.gingi-pak.com 800-437-1514</p> <p>1 oz. (30 gm) Made in USA Banana</p>
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GingiCaine Gel Banana-Hakusui



- 1 [Precautions]
Read precautions for use on the package insert carefully before use.
Precaution - Use only with a prescription of a doctor.

- 2 Marketing Authorization Holder
Hakusui Trading Co., Ltd.
532-0033
1-15 Niitaka 1-chome, Yodogawa-ku, Osaka

- 3 Topical Anesthetics for dental use
Gingicaine-Gel 20 %
Banana Flavored 30g

- 4 Medical Drug Approval no.

- 5 Active ingredient and quantity
In 100g of this product:
Japanese Pharmacopoeia
Ethyl Aminobenzoate ... 20g

- 6 Manufacturing no. (LOT)

- 7 Expiry date (EXP)

GINGICAIN GEL

gingicaine gel banana flavor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-035
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

Inactive Ingredients

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

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-035-03	1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/1993	
2	NDC:10129-035-05	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/1993	
3	NDC:10129-035-01	1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/07/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/06/1993	

Revised: 12/2021

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