GINGICAINE GEL STRAWBERRY- gingicaine gel strawberry flavor gel Gingi-Pak a Division of the Belport

Gingicaine Gel, Strawberry

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.

Precaution Section

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.

Indications and usage section

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

Active Ingredient - Benzocaine, 20%

Active ingredient	Purpose
Benzocaine 20% w/v	Oral Anesthetic

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 heat rate ◆ Shortness of breath ◆ Dizziness or lightheadedness ◆ Fatigue or lack of energy. **Do not use in children under 2 years of age.**

Consult a doctor promtly

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.

Do not use

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 allery to any "caine" local anesthetics or FD&C Red #40.

Avoid excessive heat

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

Inactive ingredients

Polyethylene Glycol 3350

Polyethylene Glycol 400

Potassium Sodium Saccharate

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

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.

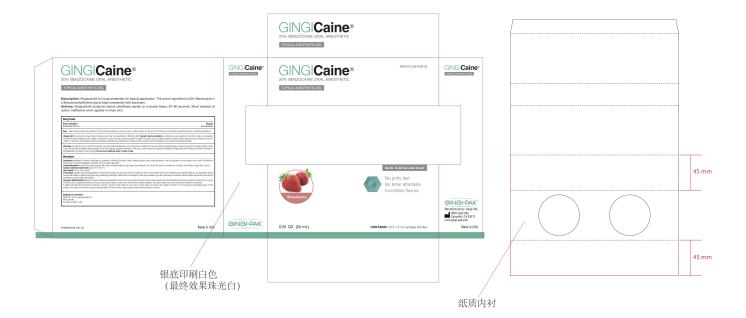
Strawberry Label USA



GingiCaine Gel Syringe label



GingiCAINE in Syringe Box



GINGICAINE GEL STRAWBERRY

gingicaine gel strawberry flavor gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10129-036

Route of Administration ORAL, DENTAL, PERIODONTAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
BE	NZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg

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

Product Characteristics			
Color	red (Strawberry Flavor)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129- 036-01	1 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/1993	
2	NDC:10129- 036-04	20 in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	01/11/2018	
3	NDC:10129- 036-05	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/1993	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	07/06/1993	

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

Revised: 12/2023 Gingi-Pak a Division of the Belport