GINGICAINE GEL VARIETY PAK- gingicaine gel variety pak 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, Variety Pak

Active Ingredients

Active ingredient	Purpose
Benzocaine 20% w/v	Oral Anesthetic

Inactive Ingredients

Polyethylene Glycol 3350

Polyethylene Glycol 400

Potassium Sodium Saccharate

Warnings

Warnings For external use only.

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 contraindications

Contraindications Should not be used in patients with history of hypersensitivity to ester-type local anesthetics.

Allergy alert Do not use if you have history of allery to any "caine" local anesthetics or FD&C Red #40.

Allergy alert Do not use if you have history of allery 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).

Gingicaine Gel Variety Pak Labels

GINGICAINE GEL VARIETY PAK

gingicaine gel variety pak gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10129-070
Route of Administration	DENTAL, ORAL, 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
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	20 mg
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	520 mg

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY, STRAWBERRY, BANANA, PINEAPPLE (Pina Colada) , COTTON CANDY, CHOCOLATE (Chocolate Mint)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10129-070-01	6 in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/09/2014	

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

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