BENCOCAINE TOPICAL ANESTHETIC- benzocaine gel Benco Dental

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.

Active Ingredients

Benzocaine 200 mg (in each g)

Purpose

Oral Anesthetic

For oral mucosal use only, as directed by dentist. For the temporary relif of pain due to minor dental procedures.

Warnings

Warnings MethemoglollInemla warning: Use of this product may cause methemoglobinemia, a seriouscondit~n that must be treated promptly because tt reduces the amount of oxygen carried in the blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy Alert

Allergy Alert Do not use on patients with a history of allergies to local anesthetics suchasprocaine,butacaine, benzocaine or other "caine" anesthetics.

Do not use

•for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or worsens; or if swelling, rash or fever develops, see your physician promptly.

- for teething
- in children under 2 years of age

When using this product

Avoid contact with eyes. If contact occurs, flush with water.

Do not exceed recommended dosage

If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding,

ask a physician before use.

Keep out of reach of children

Directions

Apply only amount needed to the oral mucosa to prevent or relieve pain.
children under 2 years of age: do not use

Other Information

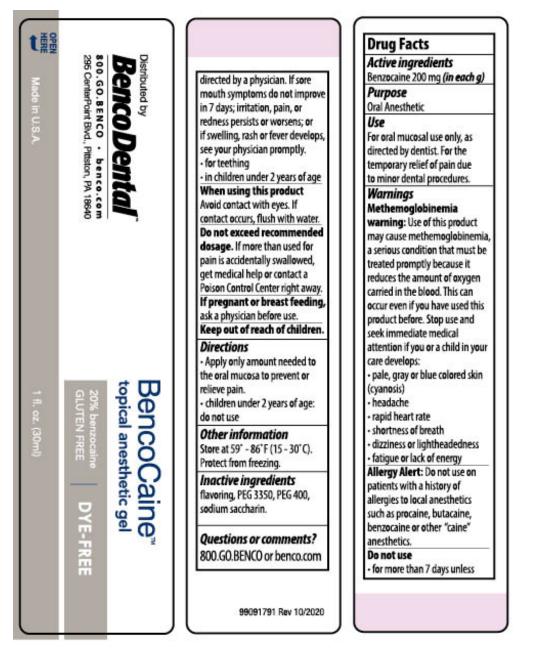
Store at 59 -86°F(15-30°C). Protect from freezing.

Inactive Ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin.

Questions or Comments?

800.GO.BENCO or benco.com



BENCOCAINE TOPICAL ANESTHETIC benzocaine gel **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:66975-340 **Route of Administration** DENTAL **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 3350 (UNII: G2M7P15E5P)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
Product Characteristics				
Color	white (DYE-FREE)	:	Score	
Shape			Size	
Flavor	CHERRY	l	Imprint Code	
Contains				
Packaging				
# Item Code	Package Description	r	Marketing Start Date	Marketing End Date
	DC:66975-340- DC:66975-340- Product 10/01/2020			
Marketing Information				
Marketing Category	Application Number or Monogra Citation	bh	Marketing Start Date	Marketing End Date
OTC monograph not final	part356		10/01/2020	

Labeler - Benco Dental (015108087)

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