BENCOCAINE TOPICAL ANESTHETIC- benzocaine gel Benco Dental

Active Ingredients

Benzocaine 200mg (in each g)

Purpose

Oral Anesthetic

Use

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

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it 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: Do not use on patients with a history of allergies to local anesthetics such as procaine, 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 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.

Directions

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

Keep out of reach of children.

Other Information

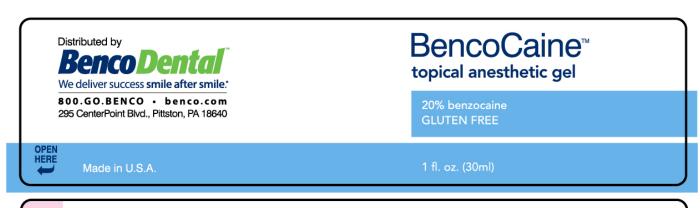
Store at 59°-86°F (15°-30°C). Protect from freezing.

Inactive Ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

Questions or comments?

800.GO.BENCO or benco.com



99091771 Rev 06/2018 mouth symptoms do not improve If pregnant or breast feeding, f swelling, rash or fever develops Keep out of reach of children. in children under 2 years of age Do not exceed recommendec (tartrazine), yellow #6, as a color contact occurs, flush with water. Poison Control Center right away #3, red #28, red #40, yellow #5, **Questions or comments?** 800.GO.BENCO or benco.com Apply only amount needed to redness persists or worsens; or dosage. If more than used for children under 2 years of age Store at 59° - 86° F (15 - 30° C). sodium saccharin. May contair directed by a physician. If sore pain is accidentally swallowed the oral mucosa to prevent or get medical help or contact a flavoring, PEG 3350, PEG 400, blue #1, green #3, green #5, see your physician promptly When using this product in 7 days; irritation, pain, or Avoid contact with eyes. If ask a physician before use. Inactive ingredients Other information Protect from freezing. · for teething relieve pain. do not use

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BENCOCAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66975-353

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)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
D&C RED NO. 28 (UNII: 767IP0Y5NH)		
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)		

Product Characteristics			
Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

ı	Pā	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:66975-353- 30	30 g in 1 JAR; Type 0: Not a Combination Product	06/01/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M022	06/27/2014		

Revised: 1/2025 Benco Dental