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 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

BencoCaine[®] Distributed by topical anesthetic gel We deliver success smile after smile: 800.GO.BENCO · benco.com 20% benzocaine 295 CenterPoint Blvd., Pittston, PA 18640 **GLUTEN FREE** OPEN Made in U.S.A. 99091771 Rev 06/2018 mouth symptoms do not improve ^c swelling, rash or fever develops, f pregnant or breast feeding, Do not exceed recommended in children under 2 years of age (eep out of reach of children. contact occurs, flush with water. Poison Control Center right away tartrazine), yellow #6, as a color #3, red #28, red #40, yellow #5, blue #1, green #3, green #5, red Questions or comments? 800.GO.BENCO or benco.com Apply only amount needed to children under 2 years of age: redness persists or worsens; or dosage. If more than used for pain is accidentally swallowed, store at 59° - 86°F (15 - 30°C). sodium saccharin. May contain directed by a physician. If sore the oral mucosa to prevent or get medical help or contact a lavoring, PEG 3350, PEG 400, 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 Directions relieve pain do not use additive. may cause methemoglobinemia a serious condition that must be attention if you or a child in your Benzocaine 200 mg *(in each g)* occur even if you have used this pale, gray or blue colored skin dizziness or lightheadedness reduces the amount of oxygen warning: Use of this product Allergy Alert: Do not use on for more than 7 days unless carried in the blood. This can product before. Stop use and For oral mucosal use only, as temporary relief of pain due allergies to local anesthetics reated promptly because it such as procaine, butacaine to minor dental procedures benzocaine or other "caine" directed by dentist. For the fatigue or lack of energy patients with a history of Aethemoglobinemia seek immediate medical lctive ingredients shortness of breath **Drug Facts** rapid heart rate **Dral Anesthetic** care develops: Varnings Do not use headache anesthetics. Purpose cyanosis) Use

BENCOCAINE TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66975-350

Route of Administration

DENTAL

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Ingredient Name BENZOCAINE (UNII: U3RS Y48 JW5) (BENZOCAINE - UNII:U3RS Y48 JW5)					Basis of Strength BENZOCAINE		Strength
							200 mg in 1 g
Inactive Ingredient	S						
		Ingredien	t Name				Strength
POLYETHYLENE GLYC	OL 3350 (U	JNII: G2M7P15E5P)					
POLYETHYLENE GLYC	OL 400 (UN	NII: B697894SGQ)					
SACCHARIN SODIUM (U	UNII: SB8ZUZ	X40 TY)					
FD&C YELLOW NO.5 (UNII: I753WE	32F1M)					
FD&C YELLOW NO.6	UNII: H77VE	I93A8)					
FD&C RED NO.3 (UNII: I	PN2ZH5LOQ	(Y)					
FD&C RED NO.40 (UNII:	: WZB9127X	OA)					
FD&C BLUE NO. 1 (UNII:	: H3R47K3TI	3D)					
FD&C GREEN NO. 3 (UN	III: 3P3ONR6	01S)					
D&C RED NO. 28 (UNII: 7	767IP0Y5NH)					
D&C GREEN NO.5 (UNII	: 8 J6 RDU8 L						
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Labeler - Benco Dental (015108087)

Revised: 11/2018

Benco Dental