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

Distributed by BencoDental We deliver success smile after smile:

800.GO.BENCO • benco.com 295 CenterPoint Blvd., Pittston, PA 18640

BencoCaine[™] topical anesthetic gel

20% benzocaine GLUTEN FREE

HERE Made in U.S.A.

fl. oz. (30ml)

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	800.GO.BENCO or benco.com
	00001771 Rev 06/2018

BENCOCAINE TOPICAL ANESTHETIC

benzocaine gel

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Product Information					
Product Type	HUMAN OTC DRUG	Item Code	ode (Source) NDC:66975-354		
Route of Administration	DENTAL				
Active Ingradiant/Active	Majaty				
Active Ingredient/Active	Molety				
Ingredient Name			Basis of Stren	gth	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)			BENZOCAINE		200 mg in 1 g
Inactive Ingredients					
	Ingredient Name				Strength
POLYETHYLENE GLYCOL 3350 (JNII: G2M7P15E5P)				
POLYETHYLENE GLYCOL 400 (UI	NII: B697894SGQ)				
SACCHADIN CODILIM /LINIL CD07					
SACCHARIN SODIUM (UNII: SB8Z	JX40TY)				
FD&C YELLOW NO. 5 (UNII: 1753)					

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)							
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)							
FD&C RED NO. 40 (UNII: WZ B9127XOA)							
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)							
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)							
D&C RED NO. 28 (UNII: 767IP0Y5NH)							
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)							
Product Characteristics							
Color orange	Score						
Shape	Size	Size					
Flavor MANGO	Imprint	Imprint Code					
Contains							
Packaging							
		Marketing Start	Marketing End				
# Item Code Package Descript	ion	Date	Date				
1 NDC:66975-354- 30 g in 1 JAR; Type 0: Not a Com Product	bination 06	5/01/2018					
Marketing Information							
	Monograph	Markating Ctart	Markating Fad				
Marketing Application Number or Category Citation	Monograph	Marketing Start Date	Marketing End Date				
OTC monograph not part356		06/27/2014					
final		00/2//2014					

Labeler - Benco Dental (015108087)

Revised: 1/2022

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