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	(Source)	NDC:66975-357		
Route of Administration	DENTAL				
Active Ingredient/Active	Moietv				
					Strength
Ingredient Name				gth	-
BENZOCAINE (UNII: U3RSY48JW5)	BENZOCAINE		200 mg in 1 g		
Inactive Ingredients					
	Ingredient Name				Strength
POLYETHYLENE GLYCOL 3350 (
POLYETHYLENE GLYCOL 400 (UI					
SACCHARIN SODIUM (UNII: SB8Z	JX40TY)				
FD&C YELLOW NO. 5 (UNII: 1753)	VB2F1M)				
FD&C YELLOW NO. 5 (UNII: 1/53)	NR5LTM)				

EDSC VELLOW NO						
FD&C YELLOW NO.						
FD&C RED NO. 3 (UN		•				
FD&C RED NO. 40 (U						
FD&C BLUE NO. 1 (L		•				
FD&C GREEN NO. 3	(UNII: 3P3ONR6	01S)				
D&C RED NO. 28 (UN	NII: 767IP0Y5NH)				
D&C GREEN NO. 5 (U	UNII: 8J6RDU8L9	X)				
Product Charac	teristics					
Color	red		Score	9		
Shape			Size			
Flavor	RASP	BERRY	Impri	nt Code		
Flavor Contains	RASP	BERRY	Impri	nt Code		
	RASP	BERRY	Impri	nt Code		
	RASP	BERRY	Impri	nt Code		
Contains	RASP	BERRY	Impri	nt Code		
					Markotin	. End
Contains Packaging		BERRY		nt Code Marketing Start Date	Marketing Date	-
Contains Packaging # Item Code	Pack			Marketing Start Date		-
Contains Packaging # Item Code 1 NDC:66975-357- 3	Pack	age Description		Marketing Start		-
Contains Packaging # Item Code 1 NDC:66975-357- 3	Pack 30 g in 1 JAR; Ty	age Description		Marketing Start Date		-
Contains Packaging # Item Code 1 NDC:66975-357- 3	Pack 30 g in 1 JAR; Ty	age Description		Marketing Start Date		-
Contains Packaging # Item Code 1 NDC:66975-357- 30	Pack 30 g in 1 JAR; Ty Product	age Description /pe 0: Not a Combination		Marketing Start Date		-
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Labeler - Benco Dental (015108087)

Revised: 1/2022

Benco Dental