BURKHART TOPICAL ANESTHETIC- benzocaine gel Burkhart Dental Supply Inc

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.

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.

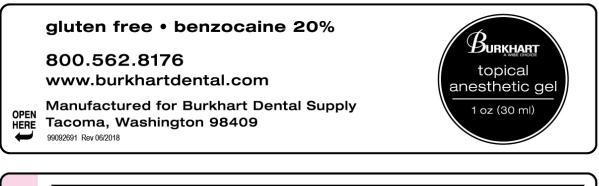
Inactive Ingredients

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

Questions of comments?

1.800.562.8176

www.burkhartdental.com



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BURKHART TOPICAL ANESTHETIC

benzocaine gel

Product Information							
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Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDC	43498-314		
Route of Administration	DENTAL						
Active Ingredient/Active Moiety							
Ingre	dient Name		Basis of Stren	gth	Strength		
BENZOCAINE (UNII: U3RSY48JW5	(BENZOCAINE - UNII:U3RSY	48JW5)	BENZOCAINE		200 mg in 1 g		
Inactive Ingredients							
	Ingredient Name				Strength		
	27XOA)						
FD&C RED NO. 40 (UNII: WZB91)							
FD&C RED NO. 40 (UNII: WZB91) FD&C BLUE NO. 1 (UNII: H3R47K							

D&C RED NO. 28 (U	NII: 767IP0Y5NH)		
D&C GREEN NO. 5 (· .		
POLYETHYLENE GL	(COL 3350 (UNII: G2M7P15E5P)		
POLYETHYLENE GL	(COL 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 (U	NII: PN2ZH5LOQY)		
Product Charac			
Color	yellow Score		
Shape	Size		
Flavor	PINEAPPLE (PINA COLADA)	Imprint Cod	e
Contains			
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	30 g in 1 JAR; Type 0: Not a Combination Product	06/01/2018	
Marketing I	nformation		
Marketing In Marketing Category	nformation Application Number or Monograp Citation	h Marketing Star Date	t Marketing End Date
Marketing	Application Number or Monograp	-	-

Labeler - Burkhart Dental Supply Inc (027532357)

Revised: 1/2022

Burkhart Dental Supply Inc