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.

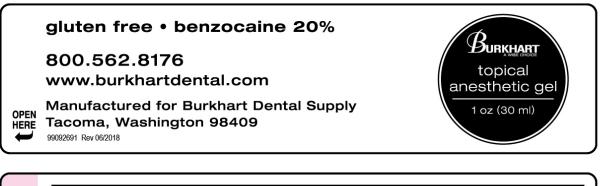
Inactive Ingredients

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

Due duet Information						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:	NDC:43498-316	
Route of Administration	DENTAL					
Active Ingredient/Active	Moiety					
Ingree	lient Name		Basis of Stren	gth	Strength	
BENZOCAINE (UNII: U3RSY48JW5)	(BENZOCAINE - UNII:U3RSY	48JW5)	BENZOCAINE		200 mg in 1 g	
Inactive Ingredients						
	Ingredient Name				Strength	
FD&C RED NO. 40 (UNII: WZB912	27XOA)					
FD&C BLUE NO. 1 (UNII: H3R47K	3TBD)					

D&C RED NO. 28 (UI	NII: 767IP0Y5NH)				
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)				
POLYETHYLENE GLY	(COL 3350 (UNII: G2M7P15E5P)				
POLYETHYLENE GLY	(COL 400 (UNII: B697894SGQ)				
SACCHARIN SODIUM	(UNII: SB8ZUX40TY)				
FD&C YELLOW NO.	5 (UNII: 1753WB2F1M)				
FD&C YELLOW NO.	6 (UNII: H77VEI93A8)				
FD&C RED NO. 3 (UI	NII: PN2ZH5LOQY)				
Product Charac	teristics				
Color	red	Scor	core		
Shape		Size	ize		
Flavor	RASPBERRY	Impr	mprint Code		
Contains					
Packaging					
# Item Code	Package Description	l	Marketing Start Date	Marketing End Date	
	30 g in 1 JAR; Type 0: Not a Combinati Product	on 06/	/01/2018		
Marketing In	nformation				
Marketing Category	Application Number or Mon Citation	ograph	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356		11/01/2015		
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Labeler - Burkhart Dental Supply Inc (027532357)

Revised: 1/2022

Burkhart Dental Supply Inc