## 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.

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## **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 #40, yellow #5, (tartrazine), yellow #6, as a color additive.

## **Questions of comments?**

1.800.562.8176

www.burkhartdental.com

#### gluten free • benzocaine 20%

800.562.8176

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HERE

Manufactured for Burkhart Dental Supply Tacoma, Washington 98409

99092691 Rev 06/2018



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Do not exceed recommended · in children under 2 years of age Poison Control Center right away. contact occurs, flush with water. pain is accidentally swallowed, dosage. If more than used for get medical help or contact a When using this product Avoid contact with eyes. If · for teething

If pregnant or breast feeding, Keep out of reach of children. ask a physician before use. Directions

Apply only amount needed to children under 2 years of age: the oral mucosa to prevent or relieve pain.

do not use

Store at 59° - 86°F (15 - 30°C). **Other information** Protect from freezing.

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# **BURKHART TOPICAL ANESTHETIC**

benzocaine gel

**Drug Facts** 

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43498-318
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)  FD&C RED NO. 3 (UNII: PN2ZH5LOQY)  FD&C RED NO. 40 (UNII: WZB9127XOA)  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)  D&C RED NO. 28 (UNII: 767IP0Y5NH)  D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)  FD&C BLUE NO. 1 (UNII: H3R47K3TBD)  FD&C GREEN NO. 3 (UNII: 3P3ONR601S)  D&C RED NO. 28 (UNII: 767IP0Y5NH)	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
	FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
	D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Product Characteristics		
Color	yellow	Score
Shape		Size
Flavor	BANANA	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:43498-318- 30	30 g in 1 JAR; Type 0: Not a Combination Product	06/01/2018	

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part356	11/01/2015			
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date		

# Labeler - Burkhart Dental Supply Inc (027532357)

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