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 #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

www.burkhartdental.com

· in children under 2 years of age

· for teething



Manufactured for Burkhart Dental Supply Tacoma, Washington 98409

99092691 Rev 06/2018



f swelling, rash or fever develops mouth symptoms do not improve redness persists or worsens; or directed by a physician. If sore see your physician promptly. in 7 days; irritation, pain, or

If pregnant or breast feeding, Do not exceed recommended 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

Keep out of reach of children. Apply only amount needed to ask a physician before use. Directions

the oral mucosa to prevent or relieve pain.

children under 2 years of age: do not use

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

blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, sodium saccharin. May contain flavoring, PEG 3350, PEG 400, Inactive ingredients

additive.

(tartrazine), yellow #6, as a color

Questions or comments? www.burkhartdental.com 1.800.562.8176

may cause methemoqlobinemia, a serious condition that must be attention if you or a child in your Benzocaine 200 mg *(in each g)* occur even if you have used this pale, gray or blue colored skin reduces the amount of oxygen warning: Use of this product dizziness or lightheadedness product before. Stop use and **Allergy Alert:** Do not use on for more than 7 days unless For oral mucosal use only, as carried in the blood. This can temporary relief of pain due allergies to local anesthetics treated promptly because it such as procaine, butacaine, to minor dental procedures. directed by dentist. For the benzocaine or other "caine' fatigue or lack of energy patients with a history of seek immediate medical Methemoglobinemia Active ingredients shortness of breath rapid heart rate Oral Anesthetic care develops: Warnings Do not use anesthetics. Purpose headache cyanosis)

BURKHART TOPICAL ANESTHETIC

benzocaine gel

Drug Facts

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43498-310
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	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. 5 (UNII: I753WB2F1M)	
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)	

Product Characteristics		
Color	red	Score
Shape		Size
Flavor	STRAWBERRY	Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:43498-310- 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)

Revised: 1/2022 Burkhart Dental Supply Inc