## SAFCO SENSICAINE ULTRA TOPICAL ANESTHETIC GEL- benzocaine gel Safco Dental Supply Co.

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

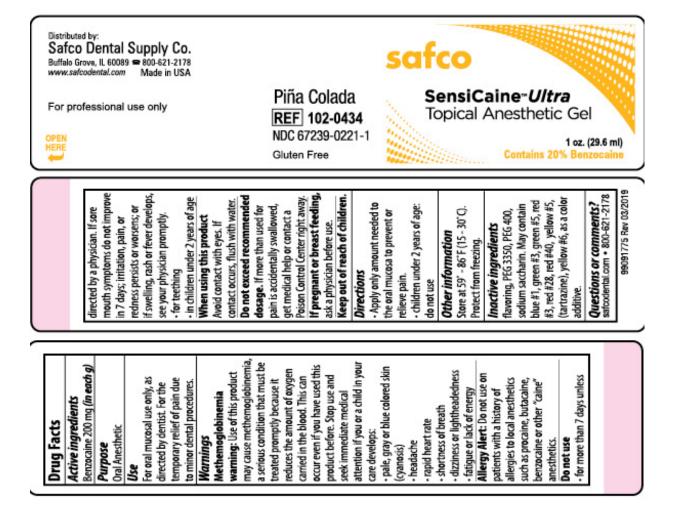
Store at 59°-86°F (15°-30°C). Protect from freezing.

#### **Inactive ingredients**

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

#### Questions or comments?

safcodental.com \* 1-800-621-2178



benzocaine gel

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:67239-0221

**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. 5 (UNII: I753WB2F1M)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
FD&C RED NO. 3 (UNII: PN2Z H5LOQY)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
<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	PINEAPPLE (Pina Colada)	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67239- 0221-1	30 g in 1 JAR; Type 0: Not a Combination Product	03/05/2019		

Distributed by: Safco Dental Supply Co. Buffalo Grove, IL 60089 ■ 800-621-2178

www.safcodental.com Made in USA

For professional use only

safco

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Directions

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children under 2 years of age

relieve pain.

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Protect from freezing.

Other information

do not use

SensiCaine~Ultra Topical Anesthetic Gel

1 oz. (29.6 ml)

99091775 Rev 03/2019

Questions or comments? safcodental.com • 800-621-2178

Contains 20% Benzocal

(tartrazine), yellow #6, as a color

additive.

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Piña Colada REF 102-0434 NDC 67239-0221-1

Gluten Free

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Warnings

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### Marketing Information

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**Drug Facts** 

Marketing information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/05/2019	

Labeler - Safco Dental Supply Co. (020417380)

Revised: 1/2022 Safco Dental Supply Co.