#### 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



enzocaine gel							
Product Informat	ion						
Product Type		HUMAN OTC DRUG Item Code (Source)		NDC:67239-0219			
Route of Administrat	tion	DENTAL				07255 0215	
Active Ingredient/	Active	Moiety					
	Ingred	ient Name B			<b>Basis of Stre</b>	Basis of Strength St	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UN			Y48JW5)		BENZOCAINE		200 mg in 1 g
Inactive Ingredier	its						
		Ingredient Name					Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)							
POLYETHYLENE GLYCO	L 400 (UI	NII: B697894SGQ)					
SACCHARIN SODIUM (U	NII: SB8Z	UX40TY)					
FD&C YELLOW NO. 5 (U	JNII: 1753V	VB2F1M)					
FD&C YELLOW NO. 6 (U	JNII: H77V	EI93A8)					
FD&C RED NO. 3 (UNII: I	PN2ZH5LC	DQY)					
FD&C RED NO. 40 (UNII:	WZ B912	7XOA)					
FD&C BLUE NO. 1 (UNII:							
FD&C GREEN NO. 3 (UN							
D&C RED NO. 28 (UNII:							
D&C GREEN NO. 5 (UNII	8J6RDU8	L9X)					
Product Characte	ristics						
Color		red	Score				
Shape			Size				
Flavor		CHERRY	Imprint Code				
Contains							
Packaging							
# Item Code	Pac	kage Description		Mar	keting Start Date	Ма	rketing End Date
1 NDC:67239- 30 g	in 1 JAR;	Type 0: Not a Combinatio	on (	03/05/2			2410

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For professional use only OPEN HERE	Cherry REF 102-0423 NDC 67239-0219-1 Gluten Free	SensiCaine Topical Anest	
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	accage. It more them 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. Xeep 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 sarchain Mav 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 + 800-621-2178
Drug Facts Active ingredients Benzocaine 200 mg (in each g) Purpose Oral Anesthetic Use For oral mucosal use only, as directed by dentist. For the temporary relief of pain due temporary relief of pain due temporary relief of pain due temporary relief of pain due temporary 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	<ul> <li>(cyanosis)</li> <li>headache</li> <li>rapid heart rate</li> <li>shortness of breath</li> <li>dizziness or lightheadedness</li> <li>fatigue or lack of energy</li> <li>Allergy Alert: Do not use on patients with a history of allergies to local anesthetics</li> </ul>	benzocaine or other "caine" anesthetics. <b>Do not use</b> • for more than 7 days unless
	mber or Monograph itation	Marketing Start Date	Marketing End Date
TC monograph not al		03/05/2019	

# Labeler - Safco Dental Supply Co. (020417380)

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Safco Dental Supply Co.