SENSICAINE TM EXTRA TOPICAL ANESTHETIC- 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.

$SensiCaine {}^{TM} Extra\ Topical\ Anesthetic\ Gel\ Strawberry\ Flavor$

Active ingridients (in each gram)

Benzocaine 200 mg

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 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 benzocaine or other "caine" anesthetics.

Sore throat warning:If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5 as a color additive.

Questions or comments?

800-621-2178

www.safcodental.com

PRINCIPAL DISPLAY PANEL - Jar Label

SAFCO

SensiCaineTM Extra

Topical Anesthetic Gel

Contains 20% Benzocaine

Strawberry Flavor

For Professional Use Only

1 oz. (34 g)



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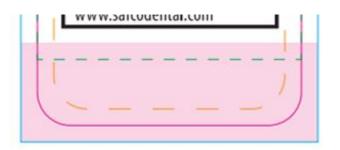
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SENSICAINE TM EXTRA TOPICAL ANESTHETIC

benzocaine gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67239-0216

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthBenzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)Benzocaine200 mg in 1 g

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| Polyethylene Glycol 3350 (UNII: G2M7P15E5P) | |
| Polyethylene Glycol 400 (UNII: B697894SGQ) | |
| Sucralose (UNII: 96K6UQ3ZD4) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| D&C GREEN NO. 5 (UNII: 8J6RDU8L9X) | |

Product Characteristics

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

| Color | red | Score | |
|--------|------------|--------------|--|
| Shape | | Size | |
| Flavor | STRAWBERRY | Imprint Code | |
| | | | |

Contains

Packaging

| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|--------------------|--|-----------------------------|---------------------------|
| ı | 1 NDC:67239-0216-1 | 29 g in 1 JAR; Type 0: Not a Combination Product | 04/30/2017 | |

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

| OTC MONOGRAPH NOT FINAL | part356 | 04/30/2017 | |
|-------------------------|---------|------------|--|
| | | | |

Labeler - Safco Dental Supply Co. (020417380)

Registrant - Safco Dental Supply Co. (020417380)

Revised: 11/2018 Safco Dental Supply Co.