

ISMILE TOPICAL ANESTHETIC- benzocaine gel
iSmile Dental Products, 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 Ingredient

Benzocaine 200mg (in each g)

Purpose

Oral Anesthetic

Use

For oral mucosa 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?

888-745-4737

Manufactured For:
iSmile Dental Products
Sacramento, CA
(888) 745-iSDP
www.iSmileDentalProducts.com



Topical Anesthetic Gel

Benzocaine 20%
GLUTEN FREE

OPEN
HERE

1oz (30ml)

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99091352 Rev 06/2018

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ISMILE TOPICAL ANESTHETIC

benzocaine gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69498-003 |
| 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 | pink | Score | |
| Shape | | Size | |
| Flavor | BUBBLE GUM | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69498-003-30 | 30 g in 1 JAR; Type 0: Not a Combination Product | 06/01/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356 | 06/01/2014 | |

Labeler - iSmile Dental Products, Inc. (016765988)