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

Topical Anesthetic Gel



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

Benzocaine 20% **GLUTEN FREE**



OPEN HERE

1oz (30ml)

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benzocaine gel

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Orug Facts

Product Information

Product Type HUMAN OTC DRUG NDC:69498-002 Item Code (Source)

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) **BENZ OCAINE** 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. 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)	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
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Product Characteristics				
Color	red	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:69498-002- 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	06/01/2014				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - iSmile Dental Products, Inc. (016765988)

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