DEFEND- benzocaine gel Mydent International

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 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

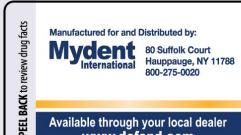
Store at 59°-86°F (15°-30°C). Protect from freezing.

Inactive ingredients

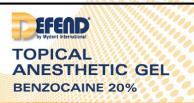
flavoring, PEG 3350, PEG 400, sodium saccharin. May contain blue #1, green #3, green #5, red #3, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

Questions or comments?

1-800-275-0020



Bonus Points **ANESTHETIC** Earn Free Gifts Save these Bonus Certificates. For further details, Log on to www.defend.com and click on Rewards Program.





GLUTEN FREE 1 oz (30 ml)

Available through your local dealer www.defend.com

in children under 2 years of age

When using this product

mouth symptoms do not improve if swelling, rash or fever develops redness persists or worsens; or directed by a physician. If sore see your physician promptly. in 7 days; irritation, pain, or for teething

Do not exceed recommended If pregnant or breast feeding Poison Control Center right away contact occurs, flush with water. pain is accidentally swallowed, **dosage.** If more than used for get medical help or contact a Avoid contact with eyes. If

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Questions or comments? additive

Rev 07/2018 99093151 -800-275-0020

Benzocaine 200 mg *(in each g)* Active ingredients **Drug Facts**

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For oral mucosal use only, as temporary relief of pain due directed by dentist. For the to minor dental procedures Methemoglobinemia Warnings

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benzocaine or other "caine" anesthetics.

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DEFEND

benzocaine gel

NDC:70721-001 HUMAN OTC DRUG **Product Type** 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

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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 Characterist	Product Characteristics		
Color	red	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:70721-001- 30	30 g in 1 JAR; Type 0: Not a Combination Product	07/01/2018	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	11/01/2014		

Labeler - Mydent International (176970747)

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