# 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.

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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

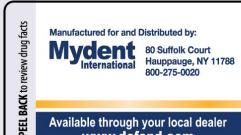
Store at 59°-86°F (15°-30°C). Protect from freezing.

# **Inactive ingredients**

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

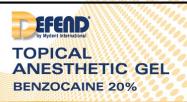
# **Questions or comments?**

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.

Keep out of reach of children





**GLUTEN FREE** 1 oz (30 ml)

Available through your local dealer www.defend.com

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

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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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**DEFEND** 

benzocaine gel

**Product Information** 

HUMAN OTC DRUG NDC:70721-005 **Product Type** Item Code (Source)

**DENTAL Route of Administration** 

**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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	FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
	D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

Product Characteristics				
Color	yellow	Score		
Shape		Size		
Flavor	PINEAPPLE (Pina Colada)	Imprint Code		
Contains				

l	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:70721-005- 30	30 g in 1 JAR; Type 0: Not a Combination Product	07/01/2018		

Marketing In	arketing 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)

Revised: 1/2022 Mydent International