

**AVANT- benzocaine gel**  
**Dharma Research, Inc.**

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**Active Ingredient**

Benzocaine, 20%

**Purpose**

Oral anesthetic

**Uses**

For the temporary relief of pain associated with canker sores and 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 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** this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "-caine" anesthetics.

**Do not use** this product for more than 7 days unless directed by a dentist or a doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash, or fever develops, see your dentist or doctor promptly.

**Do not** exceed recommended dosage.

**Keep Out of Reach of Children.** If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control center right away.

**Directions**

- Adults and children 2 years of age and older: Apply to the affected area. Use up to 4 times daily or as directed by a dentist or doctor.
- Children under 12 years of age should be supervised in the use of this product
- Children under 2 years of age: Consult a dentist or doctor.

**Other Information**

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

**Inactive Ingredients**

FD&C Red #40, FD&C Blue #1, Polyethylene glycol 3350, Polyethylene glycol 400, Saccharine sodium, Tocopheryl acetate, Xylitol

**Avant Oral Anesthetic Gel**

Gluten Free

with 20% Benzocaine, Xylitol & Vitamin E

1.12 oz (32 g)

Mint

Manufactured by Dharma Research, Inc., 5220 NW 72nd Ave, Unit 15, Miami, FL 33166

1-877-833-3725

www.avant-dental.com

## AVANT

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53045-144
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6.4 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-144-30	32 g in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/22/2021	

**Labeler** - Dharma Research, Inc. (078444642)

### Establishment

Name	Address	ID/FEI	Business Operations
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Dharma Research, Inc.		078444642	manufacture(53045-144)
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Revised: 10/2023

Dharma Research, Inc.