

**ANBESOL MAXIMUM STRENGTH- benzocaine solution**  
**Foundation Consumer Brands**

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**Anbesol<sup>®</sup>**  
**Maximum Strength**

***Drug Facts***

**Active ingredient**

Benzocaine 20%

**Purpose**

Oral pain reliever

**Uses**

- temporarily relieves pain associated with the following mouth and gum irritations:
  - toothache
  - sore gums
  - canker sores
  - braces
  - minor dental procedures
  - dentures

**Warnings**

**METHEMOGLOBINEMIA WARNING**

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in 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 this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

**Do not use**

- for teething

- in children under 2 years of age

### **When using this product**

- avoid contact with the eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor/dentist

### **Stop use and ask a doctor if**

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness lasts or worsens
- swelling, rash, or fever develops

**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 over	wipe liquid on with cotton, or cotton swab, or fingertip, apply to the affected area up to 4 times daily or as directed by a doctor/dentist
children under 12 years of age	adult supervision should be given in the use of this product
children under 2 years of age	do not use

- for denture irritation:
  - apply thin layer to the affected area
  - do not reinsert dental work until irritation/pain is relieved
  - rinse mouth well before reinserting

### **Other information**

store at 20-25°C (68-77°F)

### **Inactive ingredients**

benzyl alcohol, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, methylparaben, natural flavor, polyethylene glycol, polysorbate 80, propylene glycol, saccharin

### **Questions or comments?**

Call **1-888-594-0673** weekdays 9 AM to 5 PM EST

Distributed by: Foundation Consumer Brands, LLC  
Pittsburgh, PA 15212

## PRINCIPAL DISPLAY PANEL - 12 mL Bottle Blister Pack

MAXIMUM STRENGTH

20% Benzocaine

Anbesol<sup>®</sup>

Oral Pain Reliever/Benzocaine 20%

Instant Oral  
Pain Relief

ADA Accepted

American Dental Association

- Toothaches
- Canker Sores
- Aligner Pain
- Gum Pain

LIQUID

0.41 FL OZ (12 mL)



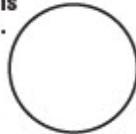


- CANKER SORES
- ALIGNER PAIN
- GUM PAIN

# LIQUID

0.41 FL OZ (12 mL)

Do not use if plastic blister or backing material is broken or separated.



HELPS TEMPORARILY RELIEVE PAIN DUE TO MOUTH SORES

AREA FOR LOT, EXPIRATION DATE



### Drug Facts

#### Active ingredient

Benzocaine 20% ..... Oral pain reliever

#### Purpose

#### Uses

- temporarily relieves pain associated with the following mouth and gum irritations:
  - toothache
  - sore gums
  - canker sores
  - braces
  - minor dental procedures
  - dentures

#### Warnings

**METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in 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 this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

#### Do not use

- for teething
- in children under 2 years of age

### Drug Facts (continued)

**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 over	wipe liquid on with cotton, or cotton swab, or fingertip, apply to the affected area up to 4 times daily or as directed by a doctor/dentist
children between 2 and 12 years of age	should be supervised in the use of this product
children under 2 years of age	do not use

- for denture irritation:
  - apply thin layer to the affected area
  - do not reinsert dental work until irritation/pain is relieved
  - rinse mouth well before reinserting

**Other information** store at 20-25°C (68-77°F)

**Inactive ingredients** benzyl alcohol, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, methylparaben, natural flavor, polyethylene glycol, polysorbate 80, propylene glycol, saccharin

For soothing — in children under 2 years of age

**When using this product**

- avoid contact with the eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor/dentist

**Stop use and ask a doctor if**

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness lasts or worsens
- swelling, rash, or fever develops

**Questions or comments?**

Call 1-888-594-0673 weekdays 9 AM to 5 PM EST

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READ AND KEEP  
CARD FOR  
COMPLETE  
WARNINGS  
AND  
INFORMATION



BCRD-0196

## ANBESOL MAXIMUM STRENGTH

benzocaine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80070-230
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SACCHARIN</b> (UNII: FST467XS7D)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:80070-230-41	1 in 1 BLISTER PACK	09/15/2021	
1		12 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	09/15/2021	

**Labeler** - Foundation Consumer Brands (117603632)

Revised: 2/2025

Foundation Consumer Brands