ANBESOL MAXIMUM STRENGTH- benzocaine gel
Foundation Consumer Brands

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.

Anbesol®
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
- to open tube, cut tip of the tube on score mark with scissors

adults and children 2 years of age and over	apply a pea-size amount 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)
- do not refrigerate

Inactive ingredients

benzyl alcohol, carbomer 934P, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, glycerin, 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 - 9 g Tube Blister Pack

MAXIMUM
20%
BENZOCAINE
STRENGTH

ANBESOL®
ORAL PAIN RELIEVER |
BENZOCAINE 20%

INSTANT ORAL
PAIN RELIEF

ADA
Accepted
American
Dental
Association ®

- ✓ TOOTHACHES
- ✓ CANKER SORES
- ✓ ALIGNER PAIN
- ✓ GUM PAIN

GEL

NET WT 0.33 OZ (9 g)

Safety Sealed Tube:
Do not use if tube tip is cut prior to opening.

ADA Accepted American Dental Association

HELPS TEMPORARILY RELIEVE PAIN DUE TO MOUTH SORES

AREA FOR LOT, EXPIRATION DATE

Drug Facts

Active ingredient — **Purpose**

Benzocaine 20% ..... 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

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

- to open tube, cut tip of the tube on score mark with scissors

adults and children 2 years of age and over	apply a pea-size amount 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

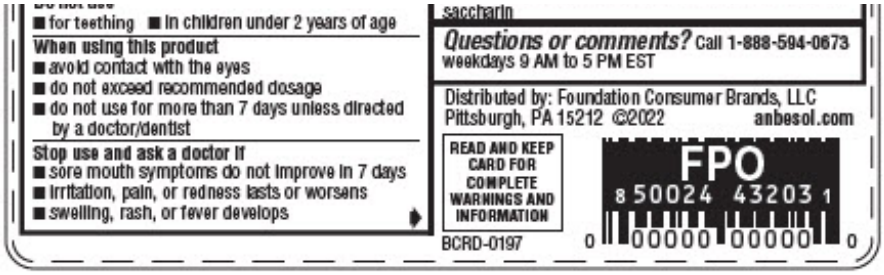
- for denture irritation:
  - apply thin layer to the affected area
  - do not reinsert dental work until irritation/pain is relieved
  - rinse mouth well before reinserting

Other information

- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

benzyl alcohol, carbomer 934P, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, glycerin, methylparaben, natural flavor, polyethylene glycol, polysorbate 80, propylene glycol,



ANBESOL MAXIMUM STRENGTH

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80070-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN (UNII: FST467XS7D)	

Product Characteristics

Color	BROWN	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:80070-220-33	1 in 1 BLISTER PACK	09/15/2021	
1		9 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/15/2021	

Labeler - Foundation Consumer Brands (117603632)

Revised: 7/2023 Foundation Consumer Brands