

BENZODENT- benzocaine cream
Focus Consumer Healthcare, LLC

Benzodent

Benzocaine 20%

Pain reliever

For the temporary relief of pain due to minor irritation of the mouth and gums caused by dentures or orthodontic appliances or injury to mouth and gums.

Adults and children 12 years and over:

- remove cap, break metal seal with cap point
- apply directly to the gums or to the denture surface that comes in contact with the affected area of the gums
- if you are using the dentures, wait a few minutes then reinsert dentures and you may use your regular denture adhesive with this product
- 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 12 years: consult a dentist or doctor

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 to 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 if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics. Localized allergic reactions may occur after prolonged or repeated use.

Do not use

- for more than 7 consecutive days unless directed by a dentist or a doctor
- for teething
- in children under 2 years of age

When using this product

- avoid contact with eyes
- do not exceed recommended dosage

Stop use and see a doctor or dentist if

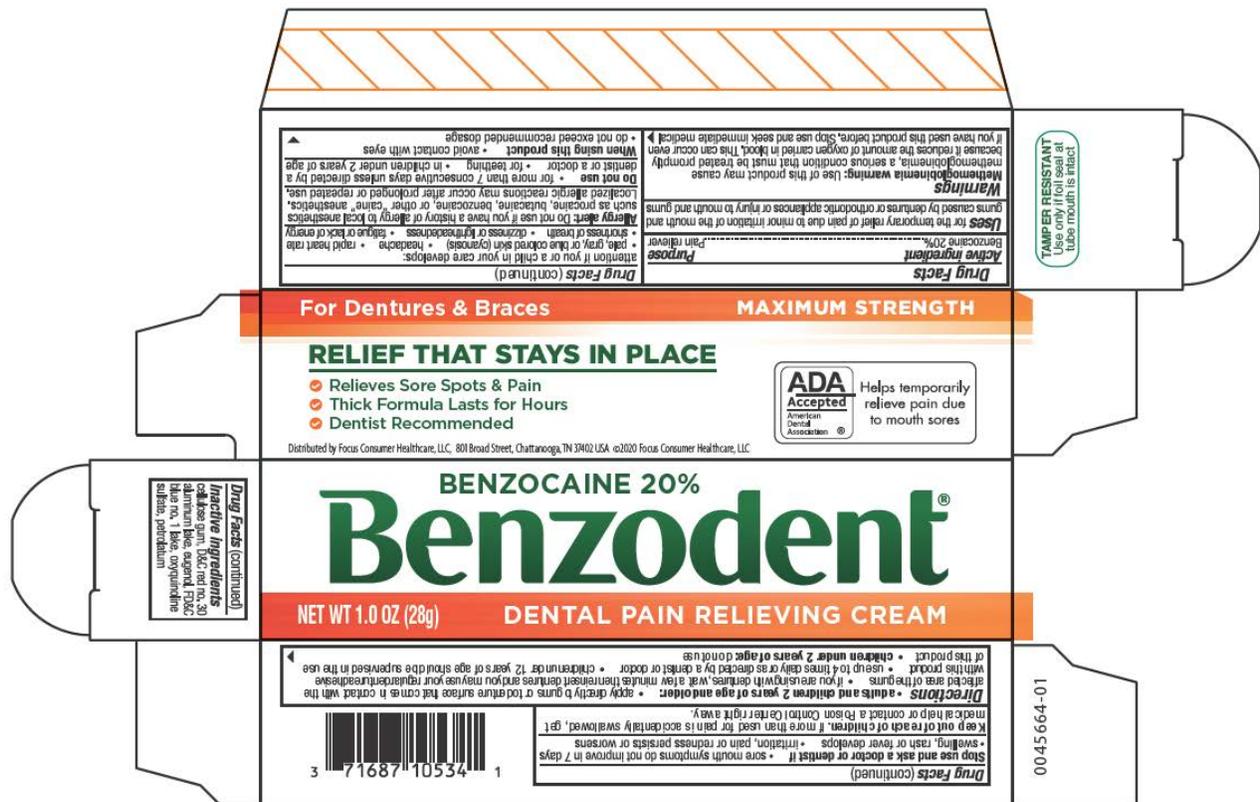
- sore mouth symptoms do not improve in 7 days
- swelling, rash or fever develops

- irritation, pain or redness persists or worsens

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

cellulose gum, D&C red no.30 lake, eugneol, FD&C blue no. 1 lake, oxyquinoline sulfate, petrolatum



BENZODENT

benzocaine cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:71687-1053

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
EUGENOL (UNII: 3T8H1794QW)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
OXYQUINOLINE SULFATE (UNII: 61VUG75Y3P)	
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71687-1053-1	1 in 1 CARTON	12/08/2017	
1		7 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:71687-1053-2	1 in 1 CARTON	12/08/2017	
2		28 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 Drug	M017	12/08/2017	

Labeler - Focus Consumer Healthcare, LLC (080743737)