

**ORAL PAIN RELIEF- benzocaine gel**  
**GERI-CARE PHARMACEUTICAL CORP**

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**ORAL PAIN RELIEF**

***Drug Facts***

**Active Ingredient**

Benzocaine 20%

**Purpose**

Oral anesthetic

**Uses**

temporary 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 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. If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- for teething
- in children under 2 years of age
- more than recommended
- for more than 7 days unless told to do so by a dentist or doctor

## When using this product

- avoid contact with the eyes

## Stop use and ask a doctor if

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

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

## Directions

- do not exceed recommended dosage
- do not use for more than 7 days unless told to do so by a dentist or doctor
- adults and children 2 years of age or older: apply to affected area up to 4 times daily or as directed by doctor/dentist
- children between 2 and 12 years of age: adult supervision should be given in use of this product
- children under 2 years of age: do not use

## Other information

- do not use tube if it is cut prior to opening
- to open tube, cut open tip of tube on score mark with scissors
- store at a controlled room temperature 68°-77°F (20°-25°C)

## Inactive ingredients

Flavor, PEG-6, PEG-8, PEG-32, PEG-75, Sodium Saccharin, Sorbic Acid

## Questions or Comments?

1-800-540-3765

**SAVE CARTON FOR COMPLETE DRUGS FACTS**

<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<b>Active ingredient</b> Benzocaine 20% .....	<b>When using this product</b> • avoid contact with the eyes
<b>Purpose</b> Oral anesthetic	<b>Stop use and ask a doctor if</b> • sore mouth symptoms do not improve in 7 days • irritation, pain, or redness persists or worsens • swelling, rash or fever develops
<b>Uses</b> temporary relieves pain associated with the following mouth and gum irritations: • toothache • sore gums • canker	<b>Keep out of the reach of children.</b>

sores • braces • minor dental procedures • dentures

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REV 1020  
Brooklyn NY 11204  
1650 63rd St.  
Gerl-Care Pharmaceuticals  
Distributed by:

NET WT. 0.5 oz. (14.2g)



**Instant Oral Pain Relief**  
**Maximum Strength**  
20% BENZOCAINE TOPICAL GEL

NDC 57896-139-05

The adult medicine for oral pain  
Tube safety sealed for your protection

**TOOTHACHE & ORAL PAIN RELIEF**  
Temporary Pain Relief for:  
• Occasional minor irritation  
• Sore mouth  
• Toothache

**INSTANT**

Compare to active ingredient  
in **Orajel® MAXIMUM**  
Toothache and Oral Pain Relief

**ORAL PAIN RELIEF**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57896-139
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 300</b> (UNII: 5655G9Y8AQ)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>POLYETHYLENE GLYCOL 1500</b> (UNII: 1212Z7S33A)	
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	

**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:57896-139-05	1 in 1 CARTON	03/01/2021	
1		14.2 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	M022	03/01/2021	

**Labeler** - GERI-CARE PHARMACEUTICAL CORP (611196254)

**Registrant** - GERI-CARE PHARMACEUTICAL CORP (611196254)

Revised: 10/2023

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