

**QUALA TOPICAL ANESTHETIC GEL- benzocaine gel**  
**National Distribution & Contracting, Inc**

*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.*

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**Active Ingredients**

Benzocaine 200mg (in each g)

**Purpose**

Oral Anesthetic

**Use**

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to 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 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 on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

**Do not use**

- for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

**When using this product** Avoid contact with eyes. If contact occurs, flush with water.

**Do not exceed recommended dosage.** If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast feeding, ask a physician before use.

## Directions

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use




Keep out of reach of children.

## Other Information

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

## Inactive Ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin, water. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

 <b>Quala.</b> DENTAL PRODUCTS Made in USA for: NDC, Inc., 407 New Sanford Road La Vergne, TN 37086   www.quala.com	<b>Topical Anesthetic Gel</b> 20% Benzocaine	 <b>Quala</b> DENTAL PRODUCTS
OPEN HERE 	<i>Quala-ty for the caring professional</i>	NET CONTENTS: 1 oz (30g) <b>Gluten Free</b>

<p>Irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.</p> <ul style="list-style-type: none"><li>• in children under 2 years of age</li></ul>	<p><b>When using this product</b> Avoid contact with eyes. If contact occurs, flush with water. Do not exceed recommended dosage. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.</p>	<p><b>If pregnant or breast feeding,</b> ask a physician before use.</p>	<p><b>Keep out of reach of children.</b></p>	<p><b>Directions</b></p> <ul style="list-style-type: none"><li>• Apply only amount needed to the oral mucosa to prevent or relieve pain.</li><li>• children under 2 years of age: do not use</li></ul>	<p><b>Other Information</b> Store at 59°- 86°F (15- 30°C). Protect from freezing.</p>	<p><b>Inactive Ingredients</b> Flavoring, PEG 3350, PEG 400, sodium saccharin, water. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.</p>	4916589 10/19
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<p><b>Drug Facts</b></p>	<p><b>Active ingredients</b> Benzocaine 200 mg (in each g)</p>	<p><b>Purpose</b> Oral Anesthetic</p>	<p><b>Use</b> For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.</p>	<p><b>Warnings</b> 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 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</p>	<p><b>Allergy Alert:</b> Do not use on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.</p>	<p><b>Do not use</b></p> <ul style="list-style-type: none"><li>• for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days;</li></ul>
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## QUALA TOPICAL ANESTHETIC GEL

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43128-034
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:43128-034-30	30 g in 1 JAR; Type 0: Not a Combination Product	10/01/2019	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	10/01/2019	

**Labeler** - National Distribution & Contracting, Inc (009831413)

Revised: 1/2022

National Distribution & Contracting, Inc