

**TOPICALE- benzocaine ointment**  
**Medical Products Laboratories, 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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**Topicale Ointment**

**Active Ingredient**

Benzocaine 18%

Oral Anesthetic

For the temporary relief of minor pain and irritation associated with minor injury of the mouth and gums, canker sores, minor dental procedures, minor irritation of the mouth and gums caused by dentures or orthodontic appliances

**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, grey or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy.

**Contraindications:**

- Do not use in large quantities or over large areas of body
- Do not use for Teething
- Do not use in children under 2 years of age

**Allergy Alert:**

Do not use if you have a history of allergy to local anesthetics such as benzocaine, butacaine, procaine or other "caine" anesthetics

**When using this product**

- Avoid contact with eyes

In case of accidental overdose, get medical help or contact a Poison Control Centre immediately

**Stop use and ask a doctor**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, swelling, rash, nausea or vomiting

If sore mouth symptoms do not improve in 7 days, or if irritation, pain or redness persists or worsens

Do not use more than directed.

Adults and children 12 years or older - Apply to the affected area. Allow to remain in place at least one minute and the spit out. Use up to 4 times daily or as directed by a dentist or doctor.

Children 2-12 years of age - Should be supervised in the use of the product

Children under 2 years of age - Do not use

- Do not use if imprinted seal under cap is broken or missing
- Store at 68° to 77° F (20° - 25° C)

Benzalkonium Chloride (as a preservative), Cetyl Alcohol, Flavorings, Polyethylene glycol, Propylene glycol, Saccharin sodium.

NDC 10733-162-35

Premier

Topicale

Topical Anesthetic Ointment

Benzocaine, 18 %

REF 9007151 35g Jar

Orange-Raspberry

Made in U.S.A.

Manufactured for: Premier® Dental Products Company,  
1710 Romano Drive, Plymouth Meeting, PA 19462 U.S.A.

Mfg: Medical Products Laboratories, Inc.

9990 Global Road Philadelphia, PA 19115 U.S.A.

0518003 Rev4 MPL 317929

Questions or Comments?

888.670.6100 or 610.239.6000

M-Th: 7:30a.m. - 5:30p.m., F: 7:30a.m. - 4:00p.m. EST

To obtain an SDS, contact Customer Service Department or visit [www.premusa.com](http://www.premusa.com).

**Retain drug facts for future reference.**

premier



**Drug Facts** (continued)

**Warnings** (continued)

**Allergy alert:** Do not use if you have a history of allergy to local anesthetics such as benzocaine, butacaine, procaine or other "caine" anesthetics.

**Stop use and ask a doctor**

- If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, swelling, rash, nausea or vomiting
- If sore mouth symptoms do not improve in 7 days, or if irritation, pain or redness persists or worsens

**When using this product**

- Avoid contact with eyes

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

**Directions**

- Do not use more than directed

Adults and children 12 years or older Apply to the affected area. Allow to remain in place at least one minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor.

**Drug Facts** (continued)

**Directions** (continued)

Children 2-12 years of age	Should be supervised in the use of the product
Children under 2 years of age	Do not use

**Other information**

- Do not use if imprinted seal under cap is broken or missing
- Store at 68° - 77° F (20° - 25° C)

**Inactive Ingredients**

Benzalkonium Chloride (as a preservative), Gcyl Alcohol, Flavorings, Polyethylene Glycol, Propylene Glycol, Saccharin Sodium

**Questions or Comments?**

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NDC 10733-162-35

premier

Topicale®

Topical Anesthetic Ointment

Benzocaine, 18%

REF 9007151 35g Jar  
Orange-Raspberry

Made in U.S.A.

**Drug Facts**

Active Ingredient	Purpose
Benzocaine, 18%	Oral Anesthetic

**Indications for use**

For the temporary relief of minor pain and irritation associated with:

- minor injury of the mouth and gums
- canker sores
- minor dental procedures
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances

**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:

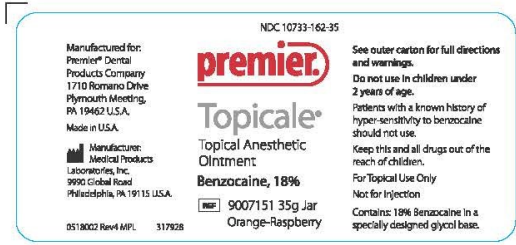
- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

**Contraindications:**

- Do not use in large quantities or over large areas of the body.
- Do not use for teething.
- Do not use in children under 2 years of age.

Manufactured for: Premier Dental Products Company,  
1710 Romano Drive, Plymouth Meeting, PA 19062 U.S.A.  
Mfg: Medical Products Laboratories, Inc.,  
9990 Global Road, Philadelphia, PA 19115 U.S.A.

0518003 Rev4 MPL 317929



## TOPICALE

benzocaine ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10733-162
<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	180 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (Orange-Raspberry)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-162-35	35 g in 1 CARTON; Type 0: Not a Combination Product	03/05/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/05/2019	

**Labeler** - Medical Products Laboratories, Inc. (002290302)

Revised: 7/2023

Medical Products Laboratories, Inc.