

TOPICALE- benzocaine gel
Medical Products Laboratories, Inc.

Topicale Gel Jar

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), D&C Red Dye # 33, Flavorings, Polyethylene Glycol, Saccharin Sodium.

NDC 10733-166-35

Premier

Topicale

Topical Anesthetic Gel

Benzocaine, 18 %

REF 9007161 35g Jar

Tropical Fruit

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.

0518005 Rev3 MPL 317931

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.

Retain drug facts for future reference.

premier



NDC 10733-166-35

premier

Topicale®
Topical Anesthetic Gel

Benzocaine, 18%

REF 9007161 35g Jar
Tropical Fruit

Made in U.S.A.

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 "aine" 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), D&C Red Dye #33 Flavorings, Polyethylene Glycol, Saccharin Sodium

Questions or Comments?

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Drug Facts

Active Ingredient

Benzocaine 18%

Purpose

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:

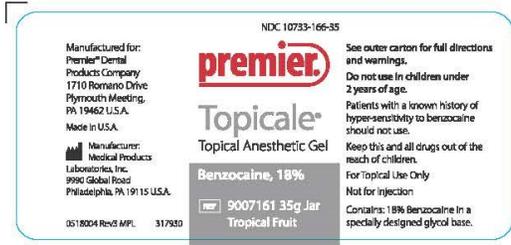
- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

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,
1770 Roman Drive, Plymouth Meeting, PA 19062 U.S.A.
Mfg. Medical Products Laboratory, Inc.,
999 Cobble Road, Philadelphia, PA 19115 U.S.A.

0518005 Rev3 MPL 317931



TOPICALE

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-166
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	180 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TROPICAL FRUIT PUNCH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-166-35	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 Drug	M022	03/05/2019	

Labeler - Medical Products Laboratories, Inc. (002290302)

Revised: 12/2024

Medical Products Laboratories, Inc.