TOPICALE- benzocaine gel
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.

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 68º to 77º F (20º - 25º 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.

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

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THE PREMIER PROMISE

Drug Facts

Active Ingredient	Purpose
Benzocaine 18%	Oral Anesthetic

Indications for use

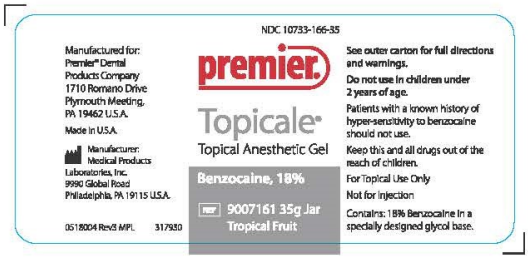
For the temporary relief of minor pain and irritation associated with
- minor injury of the mouth and gums
- canker sores
- minor dental procedures
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances

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.



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: 3WQ0SDW1A)	

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 not final	part356	03/05/2019	

Labeler - Medical Products Laboratories, Inc. (002290302)

Revised: 7/2023 Medical Products Laboratories, Inc.