

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 Pump

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.

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

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), Carbomers, D&C Red Dye # 33 (Cherry & Raspberry), FD&C Red Dye # 40 (Strawberry), Flavorings, Polyethylene glycol, Purified Water, Saccharin sodium.

Premier

Topical

Topical Anesthetic Gel

REF

9007141 Cherry

9007142 Raspberry

9007143 Strawberry

9007144 Pina Colada

9007140 Assorted

Made in U.S.A.

Contents: Three 43g Pumps

0518001 Rev4 MPL 317935

Retain drug facts for future reference.

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

Manufacturer: Medical Products Laboratories, Inc.

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

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.

For Topical Use Only - Not for Injection
 Contains: 18% Benzocaine in a specially designed glycol base.
 Warnings: Patients with a known history of hyper-sensitivity to benzocaine should not use.
 Keep this and all drugs out of the reach of children.
 Manufactured for:
 Premier® Dental Products Company
 1710 Romano Drive
 Plymouth Meeting, PA 19462 U.S.A
 www.premusa.com Made in U.S.A.


Manufacturer:
 Medical Products Laboratories, Inc.
 9990 Global Road
 Philadelphia, PA 19115 U.S.A.
 0618098 MPL Rev4 • 317938

premier®
Topicale®
 Topical Anesthetic Gel

Benzocaine, 18%


 REF 9007143 Strawberry
 43g (1.5 oz.) NET.

Peel Here for Drug Facts


 NDC 10733-171-43


Top layer

For Topical Use Only - Not for Injection
 Contains: 18% Benzocaine in a specially designed glycol base.
 Warnings: Patients with a known history of hyper-sensitivity to benzocaine should not use.
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 0618098 MPL Rev4 • 317939

premier®
Topicale®
 Topical Anesthetic Gel

Benzocaine, 18%


 REF 9007142 Raspberry
 43g (1.5 oz.) NET.

Peel Here for Drug Facts


 NDC 10733-169-43


Top layer

For Topical Use Only - Not for Injection
 Contains: 18% Benzocaine in a specially designed glycol base.
 Warnings: Patients with a known history of hyper-sensitivity to benzocaine should not use.
 Keep this and all drugs out of the reach of children.
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 0618098 MPL Rev4 • 317937

premier®
Topicale®
 Topical Anesthetic Gel

Benzocaine, 18%


 REF 9007141 Cherry
 43g (1.5 oz.) NET.

Peel Here for Drug Facts


 NDC 10733-167-43

Top layer

For Topical Use Only - Not for Injection
 Contains: 18% Benzocaine in a specially designed glycol base.
 Warnings: Patients with a known history of hyper-sensitivity to benzocaine should not use.
 Keep this and all drugs out of the reach of children.

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 9990 Global Road
 Philadelphia, PA 19115 U.S.A.
 0618098 MPL Rev4 • 317936

premier

Topicale[®]
 Topical Anesthetic Gel

Benzocaine, 18%



REF 9007144 Pina Colada
 43g (1.5 oz.) NET.

Peel Here
 for Drug
 Facts



premysa.com/premise
 NDC 10733-170-43

Top layer

premier

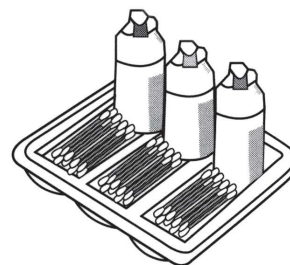
Topicale[®]

Topical Anesthetic Gel

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	
<ul style="list-style-type: none"> • Do not use for teething. • Do not use in children under 2 years of age. • Do not use in large quantities or over large areas of the body. 	
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, 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.	

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, 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.
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
<ul style="list-style-type: none"> • 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), Carboners, D&C Red Dye #33 (Cherry & Raspberry), FD&C Red Dye #40 (Strawberry), Flavorings, Polyethylene Glycol, Purified Water, Saccharin Sodium
Questions or comments? 888.670.6100 or 610.239.6000 M-Th: 7:30a.m. - 5:30p.m., F: 7:30 a.m. - 4:00p.m. EST To obtain an SDS, contact Customer Service Department or visit www.premusa.com.



Retain Drug Facts for future reference.

0518001 MPL Rev4 • 317935

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-167
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
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-167-43	43 g in 1 BOTTLE, PUMP; 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	

TOPICALE

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-170
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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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	COCONUT (Pina Colada)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-170-43	43 g in 1 BOTTLE, PUMP; 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	

TOPICALE

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-169
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-169-43	43 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/01/2019	

TOPICALE

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-171
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
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-171-43	43 g in 1 BOTTLE, PUMP; 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.