

TOPICALE XTRA- 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 Xtra Mint Freeze

Benzocaine 20%

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 light headedness, 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

1. If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, swelling, rash, nausea or vomiting
2. 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, FD&C Blue Dye # 1, FD&C Yellow Dye # 5, Flavorings, Polyethylene Glycol, Purified Water, Saccharin Sodium

Peel for Drug Facts

NDC 10733-175-01

Premier

Topicale Xtra

Topical Anesthetic Gel

Benzocaine, 20 %

REF 9007153 Mint Freeze 28.35g (1 o.z.)

For Topical Use only - Not for Injection

Contains: 20 % Benzocaine in a specially designed glycol base

Made in U.S.A.

premierdentalco.com

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.


1120048 MPL Rev5 . 2000265(00)

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

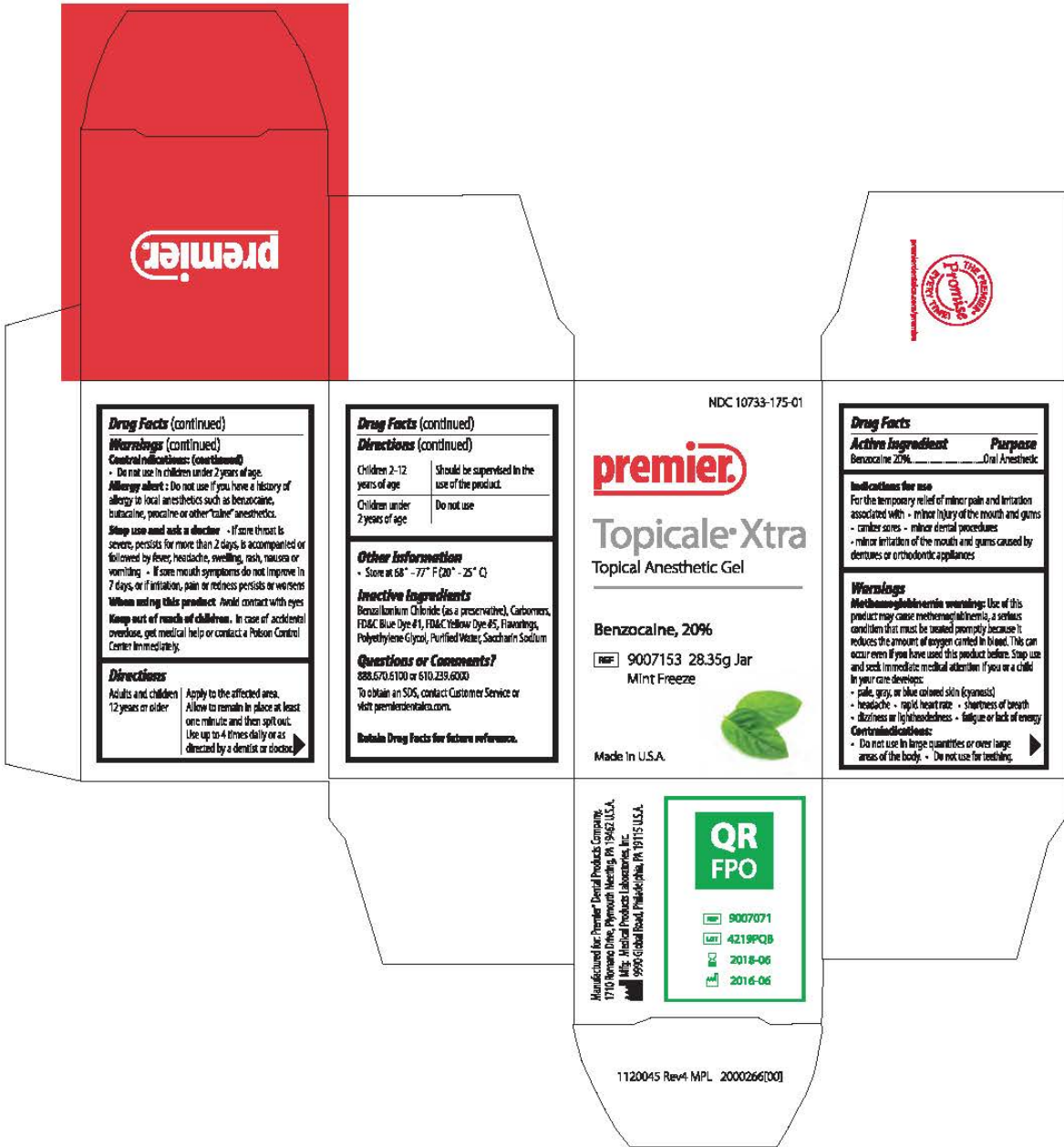
To obtain an SDS, contact Customer Service Department or visit premierdentalco.com.

<p>Drug Facts (continued)</p> <p>Directions (continued)</p> <ul style="list-style-type: none"> Do not use more than directed <p>Adults and children 12 years or older</p> <p>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.</p>	<p>Children 2-12 years of age: Should be supervised in the use of the product.</p> <p>Children under 2 years of age: Do not use</p> <p>Other Information</p> <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) 	<p>For Topical Use Only - Not for Injection</p> <p>Contains 20% Benzocaine in a specially designed glycol base.</p> <p>Manufactured for: Premier® Dental Products Company 1710 Romano Drive, Plymouth Meeting, PA 19462 U.S.A. premierdentalco.com Made in U.S.A.</p> <p>Manufacturer: Medical Products Laboratories, Inc. 9990 Global Road, Philadelphia, PA 19115 U.S.A. 1120048 MPL Rev5 • 2000265[00]</p>	<p>premier.</p> <p>Peel for Drug Facts NDC 10733-175-01</p> <p>Topical-Xtra</p> <p>Topical Anesthetic Gel Benzocaine, 20%</p> <p></p> <p>PREP 9007153 Mint Freeze 28.35g (1 oz.)</p>
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<p>Drug Facts</p> <p>Active ingredient Benzocaine 20%</p> <p>Purpose Oral Anesthetic</p> <p>Indications for use</p> <p>For the temporary relief of minor pain and irritation associated with:</p> <ul style="list-style-type: none"> 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 	<p>Drug Facts (continued)</p> <p>Warnings</p> <p>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)</p> <ul style="list-style-type: none"> headache rapid heart rate shortness of breath dizziness or lightheadedness fatigue or lack of energy 	<p>Drug Facts (continued)</p> <p>Warnings (continued)</p> <p>Contraindications:</p> <ul style="list-style-type: none"> 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. <p>Allergy alert: Do not use if you have a history of allergy to local anesthetics such as benzocaine, butylcaine, procaine or other "caine" anesthetics.</p>	<p>Stop use and ask a doctor</p> <ul style="list-style-type: none"> 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 <p>When using this product</p> <ul style="list-style-type: none"> Avoid contact with eyes <p>Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.</p>
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<p>Drug Facts (continued)</p> <p>Inactive ingredients</p> <p>Benzalkonium Chloride (as a preservative), Carbomers, FD&C Blue Dye #1, FD&C Yellow Dye #5, Flavorings, Polyethylene Glycol, Purified Water, Saccharin Sodium</p>	<p>Questions or comments?</p> <p>888.670.6100 or 610.239.5000 M-F: 7:30 a.m. - 5:30 p.m., F: 7:30 a.m. - 4:00 p.m. EST</p> <p>To obtain an SDS, contact Customer Service Department or visit premierdentalco.com.</p>
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<p>For Topical Use Only - Not for Injection</p> <p>Contains: 20% Benzocaine in a specially designed glycol base.</p> <p>Manufactured for: Premier® Dental Products Company 1710 Romano Drive, Plymouth Meeting, PA 19462 U.S.A. premierdentalco.com Made in U.S.A.</p> <p>Manufacturer: Medical Products Laboratories, Inc. 9990 Global Road, Philadelphia, PA 19115 U.S.A. 1120048 MPL Rev5 • 2000265[00]</p>	<p>premier.</p> <p>Peel for Drug Facts NDC 10733-175-01</p> <p>Topical-Xtra</p> <p>Topical Anesthetic Gel Benzocaine, 20%</p> <p></p> <p>PREP 9007153 Mint Freeze 28.35g (1 oz.)</p>
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Premier



NDC 10733-175-01

Premier

Topical Xtra
Topical Anesthetic Gel

Benzocaine, 20%

9007153 28.35g Jar
Mint Freeze



Made In U.S.A.

Drug Facts

Active Ingredient	Purpose
Benzocaine 20%	Local 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 testing.

Drug Facts (continued)

Warnings (continued)

Contraindications (continued)
- 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 "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

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

- Store at 68° - 77° F (20° - 25° C)

Inactive ingredients

Benzalkonium Chloride (as a preservative), Carbonates, FD&C Blue Dye #1, FD&C Yellow Dye #5, Flavorings, Polyethylene Glycol, Purified Water, Saccharin Sodium

Questions or Comments?

888.670.6100 or 610.238.6000
To obtain an SDS, contact Customer Service or visit premierdentals.com.

Obtain Drug Facts for future reference.

Manufactured for Premier Dental Products Company,
1710 Riverside Drive, Plymouth Meeting, PA 19062 U.S.A.
Mfg. Medical Products Laboratories, Inc.
5990 Global Road, Philadelphia, PA 19115 U.S.A.



1120045 Rev4 MPL 2000266[00]

TOPICALE XTRA

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-175
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-175-01	28.35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/22/2022	

Labeler - Medical Products Laboratories, Inc. (002290302)

