

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 Gel - Very Berry Cherry

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

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.

Benzalkonium Chloride (as a preservative), Carbomers, D&C Red Dye # 33, Flavorings, Polyethylene Glycol, Purified Water, Saccharin Sodium

Peel for Drug Facts

NDC 10733-174-01

Premier

Topicale Xtra

Topical Anesthetic Gel

Benzocaine, 20 %

REF 9007152 Very Berry Cherry 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.

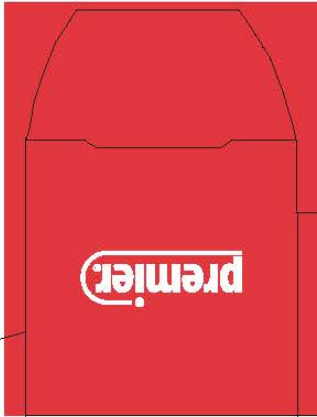
1120047 MPL Rev5 . 2000263(00)

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.



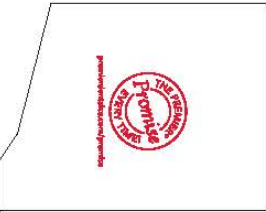
Drug Facts (continued)
Warnings (continued)
Contraindications (overdosage)
 • Do not use in children under 2 years of age.
Allergy alert - Do not use if you have a history of allergy to local anesthetics such as benzocaine, butacaine, procaine or other "aine" anesthetics.
Stop use and ask a doctor - 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, D&C Red Dye #33, Flavors, 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.

NDC 10733-174-01

Topical Xtra
 Topical Anesthetic Gel
 Benzocaine, 20%
 9007152 28.35g Jar
 Very Berry Cherry

 Made In U.S.A.




Drug Facts
Active Ingredient Benzocaine 20% **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 testing.

Manufactured for Premier Dental Products Company, 1710 Riverside Drive, Plymouth Meeting, PA 19062 U.S.A.
 Mfg. Medical Products Laboratories, Inc. 5900 Global Road, Philadelphia, PA 19115 U.S.A.


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 2018-06
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<p>Drug Facts (continued)</p> <p>Directions (continued)</p> <p>- Do not use more than directed</p> <p>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.</p>	<table border="1"> <tr> <td>Children 2-12 years of age</td> <td>Should be supervised in the use of the product</td> </tr> <tr> <td>Children under 2 years of age</td> <td>Do not use</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> Do not use if the printed seal under cap is broken or missing Store at 68° - 77° F (20° - 25° C) 	Children 2-12 years of age	Should be supervised in the use of the product	Children under 2 years of age	Do not use	<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. premierdentals.com. Made in U.S.A.</p> <p>Manufacturer: Medical Products Laboratories, Inc. 9990 Global Road, Philadelphia, PA 19115 U.S.A. 1120047 MPL Rev 5 - 2008263(D0)</p>	<p>premier.</p> <p>Topicale Xtra</p> <p>Topical Anesthetic Gel Benzocaine, 20%</p> <p></p> <p>9007152 Very Berry Cherry 28.35g (1 oz)</p> <p>Peel for Drug Facts NDC 10733-174-01</p>
Children 2-12 years of age	Should be supervised in the use of the product						
Children under 2 years of age	Do not use						

<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); headache; rapid heart rate; dizziness of breath; dizziness or lightheadedness; fatigue or lack of energy</p>	<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, butacaine, procaine or other "caine" anesthetics.</p>	<p>Stop use and seek a doctor</p> <ul style="list-style-type: none"> if you have severe, persistent 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 overdose, 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, D&C Red Dye #33, Flavorings, Polyethylene Glycol, Purified Water, Saccharin Sodium</p>	<p>Questions or comments?</p> <p>888.670.6100 or 610.238.6000 M-F: 7:30a.m. - 5:30p.m., F: 7:30 a.m. - 4:00p.m. EST</p> <p>To obtain an SDS, contact Customer Service Department or visit premierdentals.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. premierdentals.com. Made in U.S.A.</p> <p>Manufacturer: Medical Products Laboratories, Inc. 9990 Global Road, Philadelphia, PA 19115 U.S.A. 1120047 MPL Rev 5 - 2008263(D0)</p>	<p>premier.</p> <p>Topicale Xtra</p> <p>Topical Anesthetic Gel Benzocaine, 20%</p> <p></p> <p>9007152 Very Berry Cherry 28.35g (1 oz)</p> <p>Peel for Drug Facts NDC 10733-174-01</p>
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10733-174
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (Listed under NDC # 10733-175-01) , CHERRY, STRAWBERRY (Listed under NDC # 10733-176-01)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10733-174-01	28.35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/29/2022	

Labeler - Medical Products Laboratories, Inc. (002290302)