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)

Serving outsit (continued)

Control inflictions: (continued)

- De not use in children under 2 years of age.

Allowing albert : Do not use if you have a history of allowy to local anesthetics such as becausaire, butucalne, procalme or other fasher anesthetics.

bindizative productive or outer clause assertance. Strap use amanda asks a discolare - if some throat is severe, persists for more than 2 days, is accompanied of followed by fever, headache, swelling, is accompanied or followed by fever, headache, swelling in the committing. If some mouth symptoms do not improve in 7 days, or if initiation, pain or redness persists or worsen:

Youngs on in mooning him or noness persons or western Withour unding this product. And contact with eyes Komp out of rounds of children. In case of acidenta overdose, get medical help or contact a Poison Control Center Immediately.

Directions

Apply to the affected area.

Allow and children
2 years or older
Allow to remain in place at least one minute and then spit out.
Use up to 4 three daily or as directed by a dentist or doctool.

Drug Facts (continued) Directions (continued)

Children 2-12 years of age

Should be supervised in the use of the product. Do not use

Children under 2 years of age

Other Information
- Store at 68" - 77" F (20" - 25" C)

Invactive Engradients
Benzallanium Chloride (as a preservative), Carborne
D&C Red Dye #33, Ravorings, Polyednylene Glycol,
Purified Water, Saccharin Sodium

Questions or Comments? 888.670.6100 or 610.239.6000

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

ala Dray Facts for future refe

NDC 10733-174-01

premier.)

Topicale Xtra

Topical Anesthetic Gel

Benzocalne, 20%

■ 9007152 28.35g Jar Very Berry Cherry

Made In U.S.A.

Drug Facts

Active Ingradient
Benzozine 20%...... Purpose _Oral Anesthetic

Indicactions for use for the temporary relief of minor pain and instation associated with - minor highly of the mouth and gum - can be sures - minor detail procedure - minor installation of the mouth and gums caused by dentures or orthodorstic appliances

When wisings she had been a sense of this product may cause methernang his level a, a senius condition that may cause methernang his media. As senius condition that make to based promptly shecuse it reduces the amount of experi control in beach. This can carrier off pays have used this peaker defens than our senior and senior mediate medical another if pays or a child in part care devoted.

- paid, gray, or blue colered ship (spanness)

- based out in part trade - shartness of breath

- based out in part trade - shartness of breath

- Backmean in just handedness - fingle are list of energy

Controllandical desires.

- Do not use it in pays quantifies or over large arounds of the body. - Du not use it mediates.

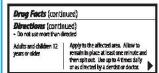
Manufectured for Permer Denial Products Company, 1710 Romano Date, Plymouth Meeting, Bn. 19462 U.S.A. Mility, Manical Products Laboratories, Inc. 1990-Global Road, Philadel phila, Rn. 19115 U.S.A.

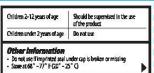


9007071 ur 4219PQB

2018-06 **2016-06**

1120044 Rev4 MPL 2000264[00]





For Topical Use Only - Not for Injection Contains: 20% Benzocaine in a specially designed glycol base. Manufactured for: Premier® Dental Products Company 1710 Romano Orive, Plymouth Meeting, PA 19462 U.S.A premierdentalco.com Made in U.S.A.

Manufacturer: Medical Products Laboratories, Inc. 9990 Global Road, Philadelphia, PA 19115 U.S.A. 1120047 MPL Rev5 - 2000263[00]





Drug Facts (continued) Menthemogle behave he washing: Use of this postular may cover machine spiderers, a periose confort in mit made be used upon the beautiful reduces the remaint of engine created in behad. This can cover even theyo have and this product before. Some use and such immediate renders interest for a dried in practice should be pay to take colored this figurests? - headcards — input hour trans—I statement of breath - Addresses or platemediates— a figure in their colored - Addresses or platemediates— a figure in their directly.

Drug Facts (continued)

Niterasings (continued)
Contrabulications:
- Do not use in large quantities or over large areas of the body.
- Do not use for teching. - Do not use far teching. - Do not use far teching. - Do not use far teching. All larger allers: Do not use if you have a history of allergy to local an such as benzocaine, butacaine, proceine or other "caine" anesthetics. Slop was mad adil: a disctor

If som threat is series, peoples for more than 7 days, is accompanied, or formed by fever, iscales, seeding, such, issues or working or follower book symptoms do not improve in 7 days, if intation, pain or advises pecision or workers.

William making the granulact

Avail contact with eyes

Heap out of reach of children. In case of accidental overder get medical help or contact a Poison Control Center immediately:

Guestions or comments? 88.670.6100 or 610.239.6000 M-Tin 7:30a.m. — 5:30pm.₈ F. 7:30 a.m. — 4:00p.m. EST Drug Facts (continued) Inactive Ingresilents
Benzalonium Chioride (as a preservative), Carbomers,
D&C Red Dye #33, Havorings, Polyethylene Glycol, Purified
Water, Saccharin Sodium To obtain an SDS, contact Customer Service Department or visit premiendentalica.com.

For Topical Use Only - Not for injection Contains: 20% Benzocaine in a specially designed glycol base. Manufactured for: Premier® Dental Products Company 1710 Romano Drive, Flymouth Meeting, PA 19462 U.S.A premierdentalco.com Made in U.S.A.

Manufacturer: Medical Products Laboratories, Inc. 9990 Global Road, Philadelphia, PA 19115 U.S.A. 1120047 MPL Rev5 + 2000263[00]



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	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 In	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)

Revised: 7/2023 Medical Products Laboratories,Inc.