

PRIME-GEL- benzocaine gel
Prime Dental Manufacturing, Inc.

Use for Oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Do not use for more than 7 days unless directed by a dentist or doctor.

See drug facts.

List of Inactive Ingredients

Flavoring, PEG3350, PEG400, sodium saccharin, water. may contain blue#, green #5, red #3, red #28, red#40, yellow #5 as color additives.

Use: for Oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Indications/Directions: Apply only amount needed to the oral mucosa to prevent or relieve pain.

See drug facts.

Keep out of reach section.

See drug facts:

Purpose: Oral Anesthetic.

See drug facts.

Active Ingredient: Benzocaine 0.2 g (200mg) per gram.

See drug facts.

Warnings

Allergy Alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Do not use for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly.

When using this product avoid contact with eyes. If contact occurs, flush with water.

Stop use and consult a health care practitioner if the following symptoms appear: weakness, confusion, headache, difficulty breathing, and/or pale, grey or blue colored skin, as these may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use.

Do not exceed recommended dosage. If more than used for pain is accidentally swallowed, get medical help or contact a poison control center immediately.

If pregnant or breast feeding, ask a health care professional before use.

Keep out of reach of children.

Contact 773-283-2914

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Package Labelling

The image shows a three-panel illustration of a Primene Cherry topical anesthetic gel package. The left panel is titled "Drug Facts" and contains the following information:

Drug Facts
Active ingredients <i>(in each gram)</i> Benzocaine 200 mg
Purpose Oral Anesthetic
Use For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.
Warnings

The middle panel shows a warning: "signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use." Below this, it states: "Do not exceed recommended dosage. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center immediately." At the bottom, it begins with "If pregnant or breast".

The right panel features a pink header that says "PEEL BACK to review drug facts". Below this is a large red cherry. The product name "Primene" is written vertically in a large font, with "Cherry" in red and "topical anesthetic gel" in a smaller font below it.

Warnings

- **Allergy Alert:** Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.
- **Do not use** for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly.
- **When using this product** Avoid contact with eyes. If contact occurs, flush with water.
- **Stop use and consult a health care practitioner** if the following symptoms appear: weakness, confusion, headache, difficulty breathing, and/or pale, grey or blue colored skin, as these may be

If pregnant or breast feeding, ask a health professional before use.

- **Keep out of reach of children.**

Directions

Apply only amount needed to the oral mucosa to prevent or relieve pain.

Other information

Store at 59° - 86°F (15 - 30°C).
Protect from freezing.

Inactive ingredients

flavoring, PEG 3350, PEG 400, sodium saccharin, water. May contain blue # 1, green #5, red #3, red #28, red #40, yellow #5 (tartrazine), as a color additive.

Questions or comments?

1-773-283-2914

Benzocaine 20%
1 oz (29.6g)



Chicago, Illinois 60641
Made in USA

LOT SLO1W
2022-11



Each gram of Prime Gel contains 200mg of Benzocaine U.S.P. Flavor, sodium saccharin U.S.P.

CAUTIONS: Keep out of reach of children. Federal (USA) Law Prohibits dispensing without prescription. For professional use only.

DIRECTIONS: FOR ORAL MUCOSA. Use only as directed by dentist. For the temporary relief of pain due to minor dental procedures.

NDC 77794-018-017

PRIME-GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77794-018
Route of Administration	DENTAL, PERIODONTAL, ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	0.2 g in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		0.69 g in 1 g		
HC RED NO. 3 (UNII: 51CPX7M1SQ)		0.0006 g in 1 g		
SACCHARIN (UNII: FST467XS7D)		0.045 g in 1 g		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)		0.05 g in 1 g		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77794-018-00	24 in 1 BOX, UNIT-DOSE	12/15/2020	
1	NDC:77794-018-17	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M022	12/15/2020		

Labeler - Prime Dental Manufacturing, Inc. (083614037)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Dental Manufacturing, Inc.		083614037	manufacture(77794-018)

Revised: 10/2025

Prime Dental Manufacturing, Inc.