

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

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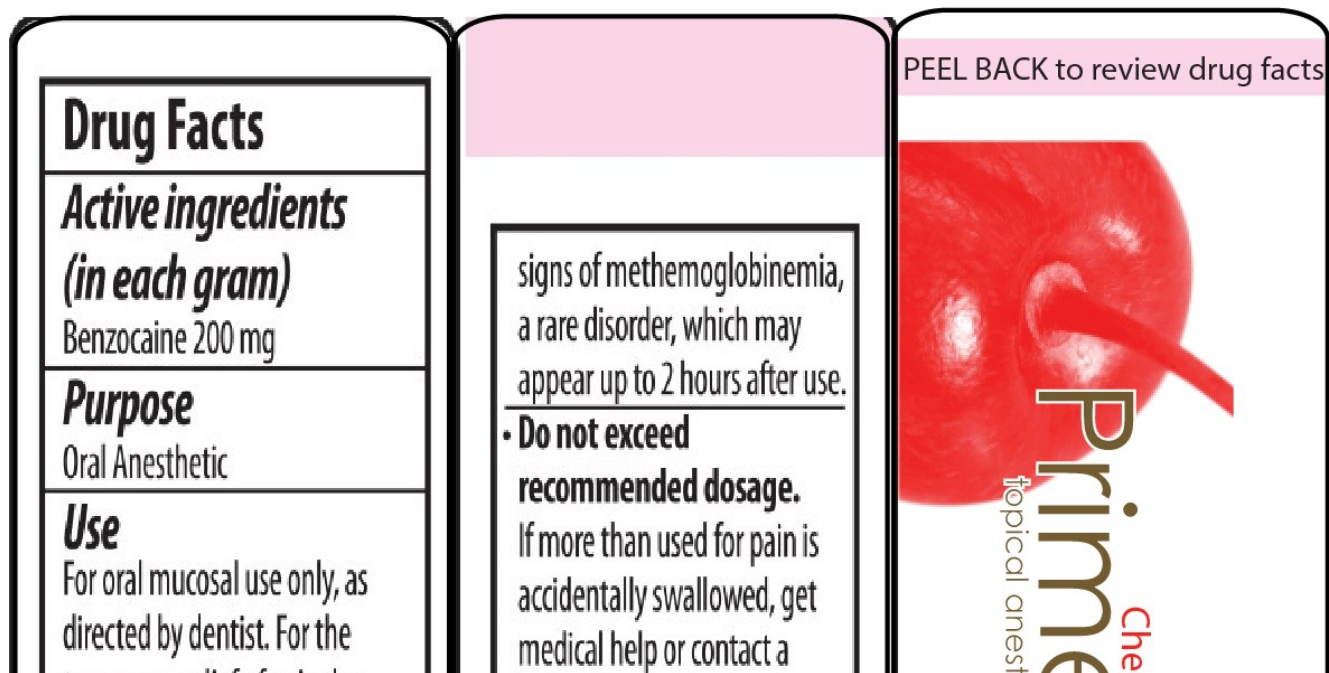
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Do not exceed recommended dosage. If more than used for pain is accidentally swallowed, get medical help or contact a poison control center immediately.

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### Package Labelling



temporary relief of pain due to minor dental procedures.

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### 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

hetic gel  
**Prime Gel**<sup>TM</sup>

Benzocaine 20%  
1 oz (29.6g)

  
**Prime Dental**  
Manufacturing Inc.  
Chicago, Illinois 60641  
Made in USA

LOT SL01W  
2022-11

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

**DIRECTIONS: FOR ORAL MUCCOSA.**  
Use only as directed by dentist.  
For the temporary relief of pain due to minor dental procedures.  
**CAUTIONS:** Keep out of reach of children. Federal (USA) Law Prohibits dispensing without prescription. For professional use only.

NDC 77794-018-017

## PRIME-GEL

benzocaine gel

### Product Information

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	0.69 g in 1 g
<b>HC RED NO. 3</b> (UNII: 51CPX7M1SQ)	0.0006 g in 1 g
<b>SACCHARIN</b> (UNII: FST467XS7D)	0.045 g in 1 g
<b>POLYETHYLENE GLYCOL 3350</b> (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 not final	part356	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: 4/2021

Prime Dental Manufacturing, Inc.