

PRODIGIUM- benzocaine 10% liquid
Price & Novelties, Inc

Prodigium

Active Ingredients: (%) Purpose

Benzocaine USP 10%.....Oral Anesthetic

Purpose

Oral Anesthetic

Uses

For temporary relief of pain associated with the following mouth and gum irritations:

- toothache
- sore gums
- cranker sores
- braces
- minor dental procedures

Warnings

Do not exceed recommended dosage

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 the 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

Allergy alert

- do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

Do not use:

- for more than 7 days unless directed by a dentist or doctor.
- For teething
- in children under 2 years of age

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breastfeeding, ask a health professional before use.

Directions

•adults and children over 12 years of age apply to the affected area. Gargle, swish around the mouth or allow to remain in place at least 1 minute and then spit out. Use up to 4 times daily or as directed by a dentist or doctor. •children under 12 years of age should be supervised in the use of the product • Children under 2 years of age: Consult a dentist or doctor

Inactive Ingredients:

polyethylene glycol

Questions or comments?

787-781-3352

Stop use and consult a doctor promptly if:

- symptoms do not improve in 7 days
- swelling, rash, or fever develop
- irritation, pain, or redness persist or worsen
- symptoms persist for more than 7 days
- allergic reaction occurs

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54361-7020-1	4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product	07/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	07/01/2024	

Labeler - Price & Novelties, Inc (091061523)

Establishment

Name	Address	ID/FEI	Business Operations
LEX, Inc		046172888	manufacture(54361-7020)

Revised: 7/2024

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