#### PRODIGIUM- benzocaine 10% liquid Price & Novelties, Inc

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### 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

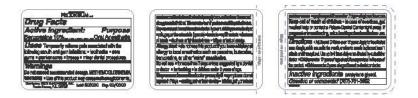
# **Questions or comments?**

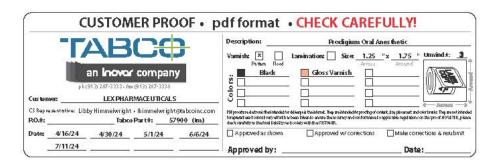
787-781-3352

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

# Prodigium





PRODIGIUM					
benzocaine 10% liquid					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:54361-7020	
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingred	ient Name		Basis of Strengt	th Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) BENZOCAINE			BENZOCAINE	10 mg in 100 mL	
Inactive Ingredients					
		Strength			
PROPYLENE GLYCOL (UNII: 6DC	9Q167V3)				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
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		
от	C Monograph Dr	ug M022	07/01/2024			

Labeler - Price & Novelties, Inc (091061523)

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

Revised: 7/2024

Price & Novelties, Inc