

BENZOCAINE 20%- benzocaine 20% solution
PAI Holdings, LLC dba PAI Pharma

Benzocaine 20% Solution

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses

for the temporary relief of occasional minor irritation, pain, sore mouth, and sore throat.

Warnings

METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but 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, 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 if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product

- avoid contact with eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a doctor or dentist

Stop using and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

Keep out of reach of children. If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- Read Directions on side panel for how to use

adults and children 2 years of age and older	apply to the affected area, Gargle, swish around in the mouth, or allow to remain in place for at least 15 seconds 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	do not use

Other information

- **do not use if foil pouch is torn or open**
- store at 15-30°C (59-86°F)

Inactive ingredients

flavor, polyethylene glycol, sucralose

Questions or comments?

call 1-800-845-8210

*This product is not manufactured or distributed by Beutlich Pharmaceuticals. LLC, the distributor of HurriCaine ONE®, and owner of the registered trademark HurriCaine ONE®, [Beutlich Pharmaceuticals, LLC does not make or license PAI's product.]

Principal Display Panel - pouch

NDC 0121-1077-01

BENZOCAINE 20% SOLUTION

Individually Wrapped Single-Unit Dose Applicator

20% Benzocaine Oral Anesthetic

CHERRY FLAVOR

Store at 15° - 30°C (59 - 86°F)

Warnings

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seek immediate medical attention if you or your child in your care develops:

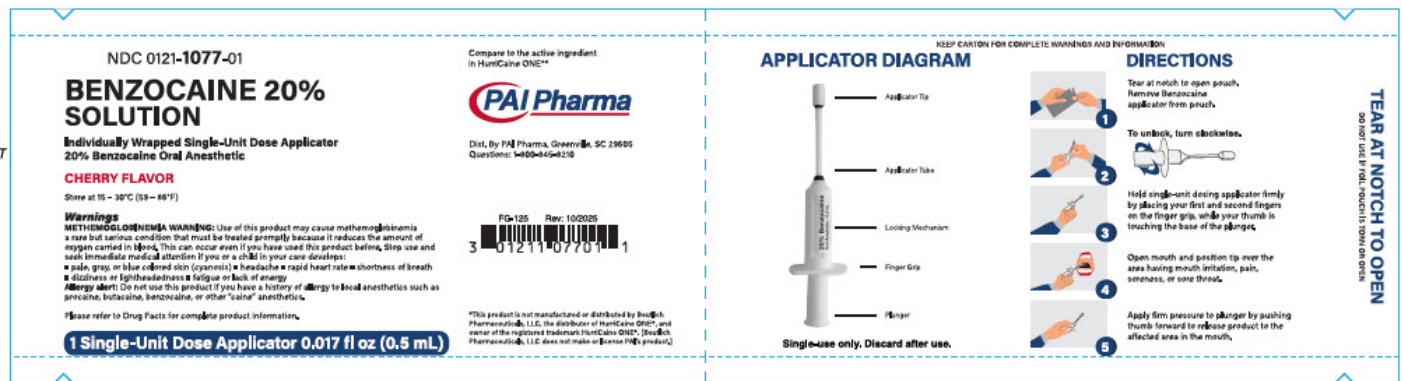
■ pale, gray, or blue colored skin (cyanosis) ■ headache ■ rapid heart rate ■ shortness of breath

■ 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.

Please refer to Drug Facts for complete product information.

1 Single-Unit Dose Applicator 0.017 fl oz (0.5 mL)



Principal Display Panel - carton

NDC 0121-1077-25

PAI Pharma Compare to the active ingredient in HurriCaine ONE®

BENZOCAINE 20% SOLUTION

Individually Wrapped Single-Unit Dose Applicator
20% Benzocaine Oral Anesthetic

CHERRY FLAVOR

25 Single-Unit Dose Applicators

0.017 fl. oz. (0.5 mL) EACH

0.425 fl. oz (12.5 mL) TOTAL



BENZOCAINE 20%			
benzocaine 20% solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-1077
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	200 mg in 1 mL
Inactive Ingredients			

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1077-25	25 in 1 CARTON	03/20/2026	
1	NDC:0121-1077-01	1 in 1 POUCH		
1		0.5 mL in 1 APPLICATOR; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	03/20/2026	

Labeler - PAI Holdings, LLC dba PAI Pharma (044940096)