

BENZOCAINE- topical anesthetic spray
Everpharm LLC

Benzocaine 20% Spray

Drug Facts

Active Ingredient

Benzocaine 20%

Purpose

Oral Anesthetic

Uses for the temporary relief of occasional minor irritation and pain associated with sore mouth and throat

Warnings

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 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 irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.

Do not use

- if foil pouch has been previously opened
- for teething
- in children under 2 years of age

When using this product

- avoid contact with eyes

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

- do not exceed recommended dosage

adults and children 2 years of age and older: 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

- store at 15-30 °C (59-86 °F)

Inactive ingredients

cherry flavor, polyethylene glycol, sucralose

Questions or comments?

(855) 879-4368

Principal Display Panel

EverPharm

NDC 84415-044-01

Benzocaine 20% Spray

Unit Dose Non-Aerosol Spray

20% Benzocaine Oral Anesthetic

25 Unit Dose Non-Aerosol Sprays

0.017 fl.oz. (0.5 mL)



NDC 84415-044-01

Compare to the active ingredient
in HurriCaine ONE**

BENZOCAINE 20% SPRAY

Unit Dose Non-Aerosol Spray
20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY FLAVOR

25 Unit Dose Non-Aerosol Sprays
0.017 fl. oz. (0.5 mL)

Principal Display Panel

EverPharm

NDC 84415-044-01

Benzocaine 20% Spray

Unit Dose Non-Aerosol Spray

20% Benzocaine Oral Anesthetic

1 Unit Dose Non-Aerosol Spray

0.017 fl.oz. (0.5 mL)



NDC 84415-044-01

Compare to the active ingredient in HurriCaine ONE®*

BENZOCAINE 20% SPRAY

Unit Dose Non-Aerosol Spray
20% Benzocaine Oral Anesthetic

ORIGINAL WILD CHERRY FLAVOR

Store at 15 - 30°C (59 - 86°F).
Do not use 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.

Distributed by:
EVERPHARM, LLC
14A Winthrop ST Marlborough,
MA 01752
(866) 838-3774

FG-103 Iss: 12/2024



1 Unit Dose Non-Aerosol Spray - 0.017 fl. oz. (0.5 mL)

*This product is not manufactured or distributed by Beutlich Pharmaceuticals, LLC, the owner of the registered trademark HurriCaine ONE®.

BENZOCAINE			
topical anesthetic spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84415-044
Route of Administration	PERIODONTAL, DENTAL		
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)			
CHERRY (UNII: BUC5I9595W)			
Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84415-044-01	25 in 1 PACKAGE	01/15/2025	
1		1 in 1 POUCH		
1		0.5 mL in 1 APPLICATOR; 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	01/15/2025	

Labeler - Everpharm LLC (119288836)

Revised: 1/2025

Everpharm LLC