

BENZ O STHETIC- benzocaine spray

Geritrex LLC

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.

Benz-O-Sthetic Spray

Drugs Facts

Active Ingredients	Purpose
Benzocaine 20%.....	Oral Anesthetic

Uses

Topical anesthetic for the temporary relief of occasional minor irritation and pain, associated with:
canker sores

- sore mouth and throat
- minor dental procedures
- minor irritation of the mouth and gums caused by dentures or orthodontic appliances
- minor injury of the mouth and gums

Directions

May be used with extension tube for finer direct application. For adults and children 2 years and older anesthetic use in mouth or throat:

Pump spray 2-3 times up to 4 times. Repeat if needed for larger areas. Anesthetic effect is reached in 15-30 seconds. Children under 12 years of age should be supervised and use as directed by dentist/doctor.

Warnings

Do not use this product if patient has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics. Do not spray into or near eyes. Do not inhale.

Patient: When using extension tube, do not spray in the back of the throat unless your dentist or doctor directed you to do so.

When using this product:

- Avoid use near eyes
- Do not use more than recommended dosage
- Do not go beyond 7 days usage, unless directed by your doctor/dentist

Patient: Discontinue use and consult a physician if: sore mouth symptoms do not improve in 5 days; irritation, pain, or redness persists or worsens; swelling, rash, or fever develops.

Other Ingredients

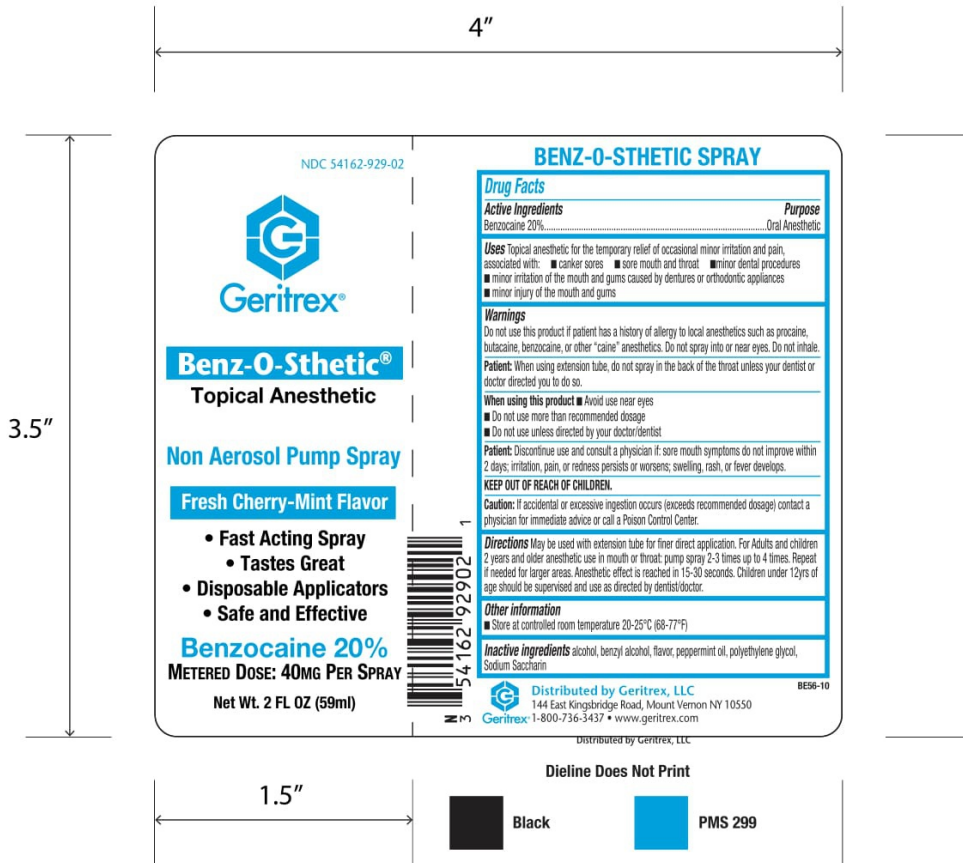
Alcohol, benzyl alcohol, flavor, peppermint oil, polyethylene glycol, sodium saccharin

Other Information:

store at controlled room temperature 20-25°C (68-77°F)

KEEP OUT OF REACH OF CHILDREN

Caution: If accidental or excessive ingestion occurs (exceeds recommended dosage) contact a physician for immediate advice or call a Poison Control Center.



BENZ O STHETIC
benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-929
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	11.8 g in 59 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (CHERRY)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-929-02	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/30/2017	

Labeler - Geritrex LLC (112796248)**Establishment**

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-929)