

BENZ O STHETIC - benzocaine spray

Geritrex Corp.

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

For control of pain; Topical anesthetic for oral or mucosal areas. To suppress the gag reflex.

Directions

May be used with extension tube for finer direct application. For anesthetic use in mouth or throat: pump spray 2-3 times or as needed. Repeat if needed for larger areas. Anesthetic effect is reached in 15-30 seconds.

Children under 6yrs of age 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:

Π Avoid use near eyes Π Do not use more than recommended dosage

Π 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

Benzyl alcohol, flavor, polyethylene glycol, SDA38B,
Sodium Saccharine

Storage

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

Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN



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BENZ O STHETIC

benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-925
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
N,N-BIS(2-HYDROXYETHYL)-P-PHENYLENEDIAMINE SULFATE (UNII: 3X5A8DP6HC)	
SACCHARIN SODIUM DIHYDRATE (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:54162-925-02	59 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/13/2012	

Labeler - Geritrex Corp. (112796248)

Revised: 2/2012

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