BENZ O STHETIC- benzocaine gel
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 Gel

Drugs Facts

Active Ingredients Purpose
Benzocaine 20% Anesthetic

Uses

For temporary relief of oral pain associated with: · toothache ·canker sores ·minor dental procedures · minor injury of the mouth and gum caused by dentures or orthodontic appliances.

Directions

Apply with cotton applicator or finger tip to affected gum area up to 4 times a day or as directed by your dentist.

Do not use for more thatn 7 days.

Warnings

Do not use this product if you have a history of allergy to local anesthetic such as Procaine, Benzocaine or other "Caines". Not recommended for children under the age of 2.

Other Ingredients

Benzyl Alcohol, Cherry Flavor, FD&C Red #40, PEG 3350, PEG 400, Sodium Saccharin

Storage

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

Keep out of reach of children

KEEP OUT OF REACH OF CHILDREN

NDC 54162-926

Benz-O-Sthetic®

Cherry Flavor Gel • Topical Anesthetic

Benzocaine 20%

NET WT. 0.5oz (15g)

Geritrex®

54162-92615 0

Drug Facts

Active Ingredients	Purpose
Benzocaine 20%	Oral Anesthetic

Uses: For temporary relief of oral pain associated with: · toothache ·canker sores ·minor dental procedures · minor injury of the mouth and gum caused by dentures or orthodontic appliances.

Warnings: Do not use this product if you have a history of allergy to local anesthetic such as Procaine, Benzocaine or other "Caines". Not recommended for children under the age of 2. Avoid eye contact. Do not exceed your doctors/dentist recommended dosage.

Directions: Adults and children over 2 years of age and older apply gel with cotton applicator or finger tip to affected gum area up to 4 times a day or as directed by your dentist. Do not use for more than 7 days unless directed by your doctor/dentist. Children 12 years and under should be supervised.

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

KEEP OUT OF REACH OF CHILDREN

Other Information: Store at controlled room temperature 20-25°C (68-77°F).

Other Ingredients: Benzyl Alcohol, Cherry Flavor, FD&C RED #40, PEG 3350, PEG 400, Sodium Saccharin

Geritrex®
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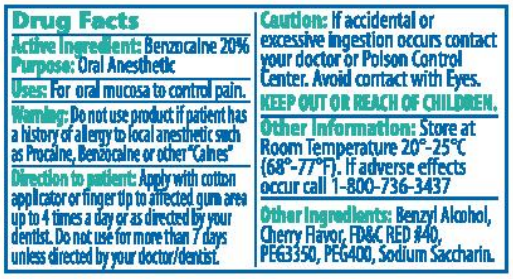

BENZ O STHETIC

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-926
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54162-926-15	15 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-926-29	29 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/31/2015	

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations

Geritrex LLC		112796248	manufacture(54162-926)