

**TOPEX- benzocaine spray, metered**  
**Dentsply LLC. Professional Division Trading as "Sultan Healthcare"**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Topex**  
**Topical Anesthetic**  
**Metered Spray**

**INDICATIONS AND USAGE**

Topical anesthetic for use on oral mucosa

**DOSAGE AND ADMINISTRATION**

Attach disposable straw to the spray valve. Spray directly on mucosa to achieve topical anesthesia.

**DOSAGE FORMS AND STRENGTHS**

Each gram of Topex 20% benzocaine topical anesthetic spray contains between 180-220 mg benzocaine. Each metered spray delivers approximately 6.8 mg of benzocaine.

**CONTRAINDICATIONS**

Should not be used in individuals with a known sensitivity to benzocaine or PABA.

**WARNINGS AND PRECAUTIONS**

**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. Stop use and seek immediate medical attention if the patient 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
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- Not for use in children under 2 years of age.
  - Keep out of reach of children.

**OVERDOSAGE**

In case of overdose, get medical help or contact a Poison Control Center right away.

## STORAGE AND HANDLING

Store between 59°-86°F (15°-30°C).

## PRINCIPAL DISPLAY PANEL - Carton

<p><b>INDICATIONS AND USAGE</b> Topical anesthetic for use on oral mucosa.</p> <p><b>DOSAGE AND ADMINISTRATION</b> Attach disposable straw to the spray valve. Spray directly on mucosa to achieve topical anesthesia.</p> <p><b>DOSAGE FORMS AND STRENGTH</b> Each gram of Topex 20% benzocaine topical anesthetic spray contains between 180-220 mg benzocaine. Each metered spray delivers approximately 6.8 mg of benzocaine.</p> <p><b>CONTRAINDICATIONS</b> Should not be used in individuals with a known sensitivity to benzocaine or PABA.</p> <p><b>WARNINGS AND PRECAUTIONS</b> <b>METHEMOGLOBINEMIA WARNING:</b> 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. Stop use and seek immediate medical attention if the patient 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.</p> <ul style="list-style-type: none"> <li>• Not for use in children under 2 years of age.</li> <li>• Keep out of reach of children.</li> </ul> <p><b>OVERDOSAGE</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>INGREDIENTS</b> Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Benzocaine, Polyethylene Glycol 400, Sodium Saccharin, Artificial Cherry Flavor</p> <p><b>STORAGE</b> Store between 59°-86°F (15°-30°C)</p>	<p>Manufactured For: Sultan Healthcare 1301 Smile Way York, PA 17404</p> <p>Toll Free: 800-637-8582 Phone: 201-871-1232 Fax: 201-871-0321 www.sultanhealthcare.com</p> <p>0031000BX, R3-072017</p>	<p><b>Dentsply Sirona</b></p> <p><b>Topex<sup>®</sup></b> Topical Anesthetic Metered Spray</p> <p>Contains: 20% Benzocaine</p> <p><b>WILD CHERRY</b></p> <p>Rx Only</p> <p><b>Net Weight: 2 oz (57g)</b></p> <p><b>REF AD31000</b> <b>NDC 0699-3100-02</b></p>	<p>Includes: 25 dispensing tips</p>  <p>Danger: Extremely flammable aerosol. Contains gas under pressure; may explode if heated. May cause an allergic skin reaction. Causes serious eye irritation.</p>
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## TOPEX

benzocaine spray, metered

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0699-3100
<b>Route of Administration</b>	PERIODONTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	220 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
BENZALDEHYDE (UNII: TA269SD04T)	
APAFLURANE (UNII: R40P36GDK6)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-3100-02	1 in 1 CARTON	01/01/1974	
1		57 g in 1 CANISTER; 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
UNAPPROVED DRUG OTHER		01/01/1974	

**Labeler** - Dentsply LLC. Professional Division Trading as "Sultan Healthcare" (167087753)

## Establishment

Name	Address	ID/FEI	Business Operations
Sciarra Laboratories, Inc.		824900369	MANUFACTURE(0699-3100)

Revised: 2/2024

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