

# LolliCaine<sup>®</sup>

Topical Anesthetic Gel

## INSTRUCTIONS FOR USE

59°–86° F  
15°–30° C



### **BUBBLE GUM** REF 360088

Contains 120 LolliPacks (0.40 g ea.)  
NDC 60640-8800

### **CHERRY** REF 360090

Contains 120 LolliPacks (0.40 g ea.)  
NDC 60640-9000

### **MINT** REF 360092

Contains 120 LolliPacks (0.40 g ea.)  
NDC 60640-9200

### **PIÑA COLADA** REF 360094

Contains 120 LolliPacks (0.40 g ea.)  
NDC 60640-9400

## DRUG FACTS

### **Active ingredient:**

Benzocaine 20%

### **Purpose:**

Oral Anesthetic

### **Uses:**

LolliCaine is a flavored topical anesthetic gel featuring rapid onset, no systemic absorption and a 15 minute duration. LolliCaine is packaged in single-dose packages for maximum asepsis and ease of use. LolliCaine is also ideal for take-home, post-operative topical pain relief. Each package contains a single dose of LolliCaine plus swab applicator.

For the temporary relief of occasional minor irritation and pain, associated with:

- Sore mouth and throat
- Ulcers
- Minor dental procedures
- Needle punctures
- Minor irritation of the mouth and gums caused by dentures or orthodontic appliances

### **Warnings:**

For external use only

### **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 any “caine” anesthetics, such as benzocaine, butacaine, procaine or tetracaine.

### **Sore Throat Warning:**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly.

### **Do Not Use:**

- For teething
- In children under 2 years of age

When using this product avoid contact with eyes

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center immediately.

### **Directions:**

Remove one LolliCaine package from the 8-unit tray. Slowly peel back the lid, exposing the cotton swab applicator and unit dose well of LolliCaine. Dip swab applicator and apply gel to mucosa or gingival soft tissue. Wait one minute or until tissue feels numb before starting needle injection or other procedure. After treatment, one or more LolliCaine applications may be used for post-operative pain or discomfort.

### **Do not exceed recommended dosage.**

### **Adults and children 2 years of age and older:**

Apply to affected area up to 4 times daily or as directed by 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 59° to 86° F (15° to 30° C)

### **Inactive ingredients:**

Blue 1\*, flavor, PEG-8, PEG-75, Red 3\*, Red 33\*, Red 40\*, sodium saccharin, Yellow 10\*

\*Contains one or more of these ingredients.

### **Questions or Comments?**

### **CENTRIX INCORPORATED**

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Making Dentistry Easier.<sup>SM</sup>

**SECTION I - Product/ Company Identification**

Product Trade Name: LolliCaine  
Common Name: 20% Benzocaine oral anesthetic

Manufacturer for: CENTRIX INC  
Address: 770 RIVER ROAD, SHELTON, CT 06484  
Emergency Telephone Number: Toll-Free (800)235-5862, (203)929-5582

**SECTION II: Hazards Identification**

Classification: Irritant.  
Adverse human health effects: May be irritating to skin. May cause sensitization by skin contact.  
GHS Classification:  
Health Environmental Physical  
Skin Sensitization Category 1(H317) Not hazardous Not hazardous

**SECTION III: SECTION III - COMPOSITION**

Hazardous Components	C.A.S.# / EC#	IUPAC Name	Substance Classification	WT%
Polyethylene Glycol	25322-68-3 / 500-038-2	Poly(oxy-1,2-ethanediyl), $\alpha$ -hydro- $\omega$ -hydroxy- Ethane-1,2-diol, ethoxylated	Not classified as Hazardous Not Classified as Dangerous	30-50
Benzocaine	94-09-7 / 202-303-5	Ethyl p-aminobenzoate	Sens 1 (H317) Xi, R43	20

The exact concentration is being withheld as a trade secret.

**SECTION IV: SECTION IV - FIRST AID MEASURES**

**4.1 Description of First Aid Measures:**

Routes of Exposure First Aid Instructions  
Eye: Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation or other symptoms persist.  
Skin: Wash skin thoroughly with soap and water. Get medical attention if symptoms develop and persist.  
Inhalation: None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.  
Ingestion: If swallowed, call a poison control center. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

**4.2 Most Important Symptoms and Effects, Both Acute and Delayed:**

Contact with skin, eyes or mucous membranes may cause numbness. Repeated skin contact may cause burning and itching of the skin with dermatitis or rash.

**4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:**

If skin sensitization occurs, discontinue use and get medical attention.  
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

**SECTION V - FIRE-FIGHTING MEASURES**

Extinguishing media: Water spray or carbon dioxide  
Special fire-fighting procedures: Use self-contained breathing apparatus  
Unusual fire and explosion hazards: none

**SECTION VI - ACCIDENTAL RELEASE MEASURES**

For large spills, wear gloves and eye protection. Small spills do not require special precautions. Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities. Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

**SECTION VII - HANDLING AND STORAGE**

For professional use only. Avoid contact with the eyes and skin. Wash thoroughly after handling. Use in accordance with package instructions. Store product in original container at cool room temperature (< 25°C) and in a dry, well-ventilated area. Avoid prolonged storage at elevated temperatures as product degradation may occur.

**SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION**

Occupational Exposure Limits: Polyethylene Glycol  
United States 10 mg/m3 TWA AIHA WEEL (aerosol)  
Germany 1000 mg/m3 (inhalable) DFG MAK  
European Union None Established  
Eye protection, hands protection, Engineering controls or other equipment:  
Safety glasses and plastic/rubber gloves

**SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES**

Physical Data: Boiling point: higher than 250°C  
Flash point: Higher than 300°F (Non-combustible liquid)  
Specific gravity: 1.091/25°C Solubility in water: Disperse  
Viscosity: 164,000 Centipoise (Brookfield, spindle #6, 5 RPM)  
Appearance and odor: Gel with color and specified flavor  
Melting point: N/A  
pH in water: 6.05  
Vapor pressure: Negligible

**SECTION X - STABILITY AND REACTIVITY**

Reactivity data: Stability: Stable in ordinary conditions  
Incompatibility: Strong oxidizing agents  
Hazardous decomposition products: Carbon dioxide and/or monoxide  
Hazardous polymerization: Will not occur  
Condition to avoid: None

**SECTION XI - TOXICOLOGICAL INFORMATION**

Potential Health Effects:  
Eyes: Direct contact may cause irritation with redness and tearing. Numbness may occur.  
Skin: Direct contact may cause numbness. Prolonged or repeated skin contact may cause contact dermatitis or hypersensitivity to benzocaine with burning, stinging, tenderness and edema.  
Ingestion: Swallowing may cause nausea, vomiting and diarrhea. In rare cases, benzocaine has been shown to cause methemoglobinemia.  
Inhalation: None expected from normal use. Inhalation of mists may cause respiratory irritation.  
Chronic Health Effects: None expected.  
Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.  
Mutagenicity: No data available  
Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.  
Acute Toxicity Data:  
Polyethylene Glycol: Oral mouse LD50 28,900 mg/kg  
Benzocaine: LD50 oral rat 3,042 mg/kg  
Reproductive Toxicity Data: No data available.  
Specific Target Organ Toxicity (STOT):  
Single Exposure: Benzocaine: When applied topically as recommended, benzocaine has been shown to be relatively nontoxic, however, sensitization may occur.  
Repeated Exposure: Propylene glycol: In 2 week inhalation study, rats were administered whole body exposure for 6 hr/day for 9 days. No exposure related clinical signs or ophthalmic changes were noted and no mortality was recorded during the study.

**SECTION XII - ECOLOGICAL INFORMATION**

Propylene glycol: Salmo salar (Atlantic salmon) >1000 mg/L  
Benzocaine: Readily biodegradable  
Benzocaine: Estimated BCF is 5. Potential for bioaccumulation is low.

**SECTION XIII - DISPOSAL CONSIDERATIONS**

Dispose in accordance with federal, state and local regulations

**SECTION XIV - TRANSPORT INFORMATION**

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None(s)	None	No
ADR/RID	None	Not Regulated	None(s)	None	No
IMDG	None	Not Regulated	None(s)	None	No
IATA/ICAO	None	Not Regulated	None(s)	None	No

**SECTION XV - REGULATORY INFORMATION**

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.  
Toxic Substances Control Act (TSCA): This product is a drug and not subject to chemical notification requirements.  
Clean Water Act (CWA): Not Listed  
Clean Air Act (CAA): Not Listed  
SARA Section 311/312 (40 CFR 370) Hazard Categories:  
Immediate Hazard: Yes Pressure Hazard: No Fire Hazard: No  
Delayed Hazard: No Reactivity Hazard: No

**SECTION XVI - OTHER INFORMATION**

Restrictions on use: to be sold to and used by dental professionals only.

**CAUTION**

The above information is based on presently available data and to our best knowledge for handling the product under normal conditions. Any use of this product in any way not indicated on this document or using it together with any other process/procedure will be exclusively under the user's responsibility

This product is covered by one or more of the following U.S. and foreign patents: 5001803; 5660273; 6116414; 6328159; 6685013; 6959808; D421,217; 077021; 1035033; 1197442; 7243789; and 3877764. Additional US and International Patents pending or granted.

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