LolliCaine®
20% Benzocaine
Topical Anesthetic Gel

BENZOCAINE & ALLERGENS FACT SHEET

LolliCaine 20% Benzocaine Topical Anesthetic Gel is effective for temporary pain relief during and after dental procedures.

Benzocaine is a topical local anesthetic (numbing medication). It works by blocking nerve signals in the body. Benzocaine is generally well-tolerated and non-toxic when applied topically, as recommended. The FDA requires that the following safety information be communicated to the public because of possible harmful side-effects when applied.

To clearly communicate the specific FDA Benzocaine advisory, Centrix has included wording on the LolliCaine packaging and on this instruction sheet for your review and understanding. It describes the symptoms a person may experience after coming in contact with Benzocaine, the limitations of how this material should be used and the appropriate age group for using this material.

BENZOCAINE SAFETY INFORMATION

Warnings:

- For external use only
- Keep out of reach of children
- In case of overdose, get medical help or contact Poison Control Center immediately

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 OR on children under 2 years of age
- On or near eyes
- If pregnant or breast-feeding – ask a health professional before use

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.

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Additional Patient Information
We recognize that the remaining ingredients in LolliCaine may be potential allergens, and have provided a list of inactive ingredients below, and on the packaging labels.

Inactive Ingredients:
PEG-8, PEG-75, sodium saccharin, Mint flavor, Cherry flavor, Bubble Gum flavor, Piña Colada flavor

LolliCaine does NOT contain Red Dye #40 or any other added colorants (dyes).

View the chart below to see common allergens which are NOT present in LolliCaine:

COMMON ALLERGENS	PRESENT IN LOLLICAINE[1]
Dairy Products (including derivatives)	No
Egg Products	No
Gluten (including wheat, barley, millet & rye)	No
Soy Products (including soy lecithin)	No
Peanut Products	No
Tree Nuts & Derivatives (including almond, Brazil nut, cashew, chestnut, hazelnut (filbert), macadamia, pecan, pine nuts, pistachio, walnut)	No
Seed Products (including sesame, sunflower, cottonseed, poppy)	No

The practice of applying 20% Benzocaine during dental restorations has a long history of safe and effective use and our LolliCaine product is part of that success story. One of our primary objectives at Centrix is to provide as much safety information as possible about our products by listing relevant cautions and contra-indications in our instructions. In those cases where we are unable to provide specific warnings for specific ingredients for specific individuals, we strongly encourage that an allergen patch screening test first be performed using our material in order to make the best for the patient.

Tim White | Regulatory Affairs Manager

[1]Although there are no allergens present in the product itself, the above allergens may be present in the same facility and/or manufacturing equipment used to produce the raw materials and/or finished product.

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