CENTRIX
LolliCaine®
20% Benzocaine

INSTRUCTIONS FOR USE

BUBBLE GUM
REF 360088 Contains 120 Lollipacks (0.40 g ea.)

CHERRY
REF 360090 Contains 120 Lollipacks (0.40 g ea.)

MINT
REF 360092 Contains 120 Lollipacks (0.40 g ea.)

PIÑA COLADA
REF 360094 Contains 120 Lollipacks (0.40 g ea.)

Topical Anesthetic Gel 20% Benzocaine
Store at 59°F - 86°F (15°C - 30°C)

LolliCaine is a flavored topical anesthetic gel featuring rapid onset, no systemic absorption, and 15-minute duration. LolliCaine is packaged in single-dose LolliPacks for maximum asepsis and ease of use. LolliPacks are also ideal to give to patients for take-home, postoperative topical pain relief. Each LolliPack® unit contains one unit dose of LolliCaine gel plus swab applicator.

Usual Dosage: For oral mucosal use only as directed by dentist.

TO USE: Remove one LolliCaine unit from the 8 unit tray. Slowly peel back the lid, exposing the cotton swab applicator and unit dose well of LolliCaine gel. Dip swab applicator and apply gel to mucosa or gingival soft tissue. Wait 1 minute or until patient feels numb before starting needle injection or other procedure. After treatment, patient may be given one or more Lollipacks to treat post-operative pain or discomfort.

INGREDIENTS: Each gram of LolliCaine 20% benzocaine gel contains 200mg of benzocaine U.S.P. in a water soluble base of P.E.G. 3350 U.S.P., P.E.G. 400 U.S.P., flavor, sodium saccharin U.S.P. and (cherry) [FD&C Red #40) (mint)[FD&C green #5)

WARNING: Do not use on patients with a known sensitivity to benzocaine or p-aminobenzoate compounds. Do not use on children under the age of 2 without the consent of a doctor as safety and efficacy have not been confirmed. Keep out of reach of children.

ADVERSE REACTIONS: All medicines may cause side effects, but many people have no, or minor, side effects. No COMMON side effects have been reported with benzocaine gel. Seek medical attention right away if any of these SEVERE side effects occur: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); mouth burning, irritation, redness, swelling, or tenderness; pale, gray or blue colored skin as these may be signs of methemoglobinemia, a rare disorder, which may appear up to 2 hours after use. This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider.

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MODE D'EMPLOI

GOMMÉ À MACHER
REF 360088C Contient 120 unités (0,40 g ch.)

CERISE
REF 360090C Contient 120 unités (0,40 g ch.)

MENTHE
REF 360092C Contient 120 unités (0,40 g ch.)

PIÑA COLADA
REF 360094C Contient 120 unités (0,40 g ch.)

Gel anesthésique topique LolliCaine avec benzocaïne à 20%.
Entreposer à 59°F - 86°F (15°C - 30°C)

LolliCaine est un gel anesthésique topique à déclenchement rapide, sans absorption systémique et d'une durée de 15 minutes. LolliCaine est emballé en LolliPacks d'unidoses pour une asepsie maximale et pour en faciliter l'utilisation. On peut donner les LolliPacks® aux patients pour apporter à la maison pour soulager la douleur postopératoire. Chaque unité LolliPack contient une unidose de gel LolliCaine avec un applicateur coton-tige.

Posologie habituelle: Pour muqueuse buccale seulement, selon les instructions du dentiste.

UTILISATION: Retirer l'unité de LolliCaine du plateau de 8 unités. Peler lentement le couvercle en exposant le coton-tige et l'unidose de gel LolliCaine. Tremper le coton-tige et appliquer le gel à la muqueuse ou au tissu mou gingival. Attendre 1 minute ou jusqu'à ce que le patient ressente un engourdissement avant de commencer une injection ou toute autre procédure. Suite au traitement, le patient peut recevoir un ou deux LolliPacks pour traiter la douleur ou l'inconfort postopératoire.

INGRÉDIENTS: Chaque gramme de LolliCaine de benzocaïne à 20 % contient 200mg de benzocaïne U.S.P. dans une base P.E.G. soluble à l'eau, 3350 U.S.P., P.E.G. 400 U.S.P., - saveur, saccharine sodique, U.S.P. et (cerise) [FD&C rouge no 40) (menthe) [FD&C vert no 5)

AVERTISSEMENT: Devrait être utilisé avec prêcaution chez les patients ayant un historique connu d'hypersensibilité aux composés de benzocaine et de paminobenzoate. Garder hors de la portée des enfants.

EFFETS INDÉSIRABLES: Tous les Médicaments peuvent provoquer des effets secondaires, mais beaucoup de gens pas, ou mineures, des effets secondaires. Pas effets secondaires communs ont été rapportés avec gel benzocaine. Consulter un médecin immédiatement si un de ces effets secondaires graves se produisent: De graves réactions allergiques (éruption cutanée, urticaire, démangeaisons, difficulté à respirer, sensation, oppression dans la poitrine, enflure de la bouche, du visage, des lévres ou de la langue), brùler la bouche, irritation, rougeur, enflure ou sensibilité. Si les symptômes suivants apparaissent, cessez de l'utiliser et consultez un professionnel de la santé : faiblesse, confusion, maux de tête, difficulté à respirer et/ou peau devenant pâle, grise ou bleue, car il peut s'agir de signes de méthémoglobinémie, une maladie rare qui peut apparaître durant les 2 premières heures d'utilisation. Ce n'est pas une liste complète de tous les effets secondaires qui peuvent survenir. Si vous avez des questions sur les effets secondaires, communiquez avec votre fournisseur de soins de santé.

centrix
Making Dentistry Easier.℠

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 Revised (Modifié) 12/2018 012007 REV J

SAFTEY DATA SHEET (SDS)

In accordance with Hazard Communication Standard (HCS), 29CFR 1910.1200(g), 2012 revision

SECTION I - Product/ Company Identification
Product Trade Name: Lollicaine
Common Name: 20% Benzocaine oral anesthetic
Part (Item) Number: REF 360088, 360090, 360092, 360094, 360088C, 360090C, 360092C, 360094C
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), α-hydro-ω-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 methemoglobemia.
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.

BUBBLE GUM **REF 360088,** NDC 60640-0088, NPN 800 16262
CHERRY **REF 360090,** NDC 60640-0090, NPN 800 16262
MINT **REF 360092,** NDC 60640-0092, NPN 800 16262
PIÑA COLADA **REF 360094,** NDC 60640-0094, NPN 800 16262

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Revised 01/2018 012007 REV J