

LOLLICAINE CHERRY- benzocaine gel, dentifrice
LOLLICAINE MINT- benzocaine gel, dentifrice
LOLLICAINE BUBBLE GUM- benzocaine gel, dentifrice
LOLLICAINE PINA COLADA- benzocaine gel, dentifrice
Centrix, Inc.

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.

**Lolicaine Topical Anesthetic Gel/Liquid –
20% Benzocaine**

Topical Anesthetic Gel 20% Benzocaine

Store at 59°F - 86°F (15°C - 30°C)

BUBBLE GUM REF 360088 Contains 120 Lollipacks (.40g each)
CHERRY REF 360090 Contains 120 Lollipacks (.40g each)
MINT REF 360092 Contains 120 Lollipacks (.40g each)
PINA COLADA REF 360094 Contains 120 Lollipacks (.40g each)

DESCRIPTION

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, post-operative topical pain relief. Each LolliPackunit contains one unit dose of LolliCaine gel plus swab applicator.

INDICATIONS & USAGE

Indicated as a topical anesthetic for use on oral mucosa prior to local anesthetic injections, scaling and prophylaxis. Also useful to relieve discomfort associated with taking impressions and intraoral radiographs.

CONTRAINDICATIONS

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

WARNINGS

Keep out of reach of children. For professional dental use only.

PRECAUTIONS

Avoid prolonged periods of storage at higher temperatures, it may cause degradation products.

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.

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.

INGREDIENTS

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]

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www.cenrtixdental.com

SECTION IV: Physical Data: Boiling point: higher than 250 Specific gravity: 1.091/25 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 V: FIRE AND EXPLOSION DATA: Flash point: Higher than 300 (Non-combustible liquid)

Extinguishing media: Water spray or carbon dioxide

Special fire-fighting procedures: Use self-contained breathing apparatus Unusual fire and explosion hazards: none

Effect of over-exposure: Inhalation of vapors may cause coughing and difficult breathing, contact with skin or eyes may cause irritation. Prolonged skin contact may cause dermatitis. Ingestion may cause headache, nausea, vomiting, gastrointestinal irritation, convulsions, and unconsciousness

Emergency and first aid procedures: Flush skin and eye contact with water for 15 minutes. If swallowed, induce vomiting at once by giving 2 glasses of water and inserting finger down throat. Call a physician. Remove contaminated clothing and wash. Discard damaged clothing. Chronic effects of over-exposure: not identified.



Bubble Gum Package label



Cherry



Mint

CENTRIX LolloCaine®
20% Benzocaine

Topical Anesthetic Gel

Mint

Contains:
120 Units (.4g per unit)



59°F-88°F (15°C-30°C)

REF 360092

TOPICAL ANESTHETIC GEL

Mint

CENTRIX LolloCaine®
20% Benzocaine

Contains: 120 Units
(.4g per unit)

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TOPICAL ANESTHETIC GEL

Pina Colada

CENTRIX LolloCaine®
20% Benzocaine

Topical Anesthetic Gel

Piña Colada

Contains:
120 Units (.4g per unit)



59°F-88°F (15°C-30°C)

REF 360094

TOPICAL ANESTHETIC GEL

Piña Colada

CENTRIX LolloCaine®
20% Benzocaine

Contains: 120 Units
(.4g per unit)

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TOPICAL ANESTHETIC GEL

LOLLICAINE CHERRY

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60640-3690
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60640-3690-1	120 in 1 BOX, UNIT-DOSE		
1		0.4 g in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

LOLLICAINE MINT

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60640-3692
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60640-3692-1	120 in 1 BOX, UNIT-DOSE		
1		0.4 g in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

LOLLICAINE BUBBLE GUM

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60640-3688
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60640-3688-1	120 in 1 BOX, UNIT-DOSE		
1		0.4 g in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

LOLLICAINE PINA COLADA

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60640-3694
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	220 mg in 1 g

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor	COCONUT (Pina Coloda)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60640-3694-1	120 in 1 BOX, UNIT-DOSE		
1		0.4 g in 1 CUP, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	

Labeler - Centrix, Inc. (053707303)

Registrant - Centrix, Inc. (053707303)

Establishment

Name	Address	ID/FEI	Business Operations
Centrix, Inc.		053707303	repack(60640-3690, 60640-3694, 60640-3692, 60640-3688)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 9/2013

Centrix, Inc.