

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

Active ingredients

Benzocaine 20%

Purpose

Oral Anesthetic

Use

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 right away.

Directions

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?

Contact

Centrix, Inc.,

770 River Rd, Shelton, CT 06484

Toll Free (800) 235-5862

TEL (203) 929-5582

FAX (203) 929-6804

www.centrixdental.com

LolliCaine[®] CENTRIX

20% Benzocaine

TOPICAL ANESTHETIC GEL

REF 360088

120 Units
(0.4 g/0.3 mL per unit)



Bubble Gum



59°F - 86°F (15°C - 30°C)



NDC: 60640-8800



Bubble Gum

LolliCaine[®] CENTRIX
20% Benzocaine

CONTAINS: 120 Units
(0.4 g/0.3 mL per unit)

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Drug Facts	Drug Facts (Contd..)
<p>Active ingredient (in each unit-dose pack): Benzocaine 20%.....Oral Anesthetic</p> <p>Purpose Use for the temporary relief of occasional minor irritation and pain, associated with: • Sore mouth and throat • Ulcers • Minor dental procedures • Waxed piercings • Alleviate irritation of the mouth and gums caused by dentures or orthodontic appliances</p> <p>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, prilocaine or tetracaine.</p> <p>See 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.</p> <p>Do Not Use • for teething • in children under 2 years of age When using this product avoid contact with eyes</p>	<p>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 right away.</p> <p>Directions 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</p> <p>Other information Store at 59° to 86° F (15° to 30° C)</p> <p>Inactive ingredients Blue 1*, flavor, PEG-8, PEG-75, Red 3*, Red 30*, Red 40*, sodium saccharin, Yellow 10* *contains one or more of these ingredients.</p> <p>Questions or comments? Contact: Centrix, Inc., 770 River Rd, Shelton, CT 06484 TEL: (203) 926-5382 TOLL FREE: (800) 235-5382 FAX: (203) 926-6804 www.centrixdental.com</p>

LolliCaine[®] CENTRIX

20% Benzocaine

TOPICAL ANESTHETIC GEL

REF 360090

120 Units
(0.4 g/0.3 mL per unit)



Cherry



59°F - 86°F (15°C - 30°C)



NDC: 60640-9000



Cherry

LolliCaine[®] CENTRIX
20% Benzocaine

CONTAINS: 120 Units
(0.4 g/0.3 mL per unit)

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Drug Facts	Drug Facts (Contd..)
<p>Active ingredient (in each unit-dose pack): Benzocaine 20% Type: Oral Anesthetic</p> <p>Use: For the temporary relief of occasional minor irritation and pain, associated with: <ul style="list-style-type: none"> • Sore mouth and throat • Ulcers • Minor dental procedures • Needle punctures • Minor irritation of the mouth and gums caused by dentures or orthodontic appliances </p> <p>Warnings For external use only</p> <p>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: <ul style="list-style-type: none"> • pale, gray or blue colored skin (cyanosis) • headache • rapid heart rate • shortness of breath • dizziness or lightheadedness • fatigue or lack of energy </p> <p>Allergy alert: Do not use if you have a history of allergy to any "caine" anesthetics, such as benzocaine, butacaine, procaine or tetracaine.</p> <p>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.</p> <p>Do Not Use <ul style="list-style-type: none"> • for soothing • in children under 2 years of age </p> <p>When using this product avoid contact with eyes</p>	<p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away.</p> <p>Directions Do not exceed recommended dosage.</p> <p>Adults and children 2 years of age and older: apply to affected areas up to 4 times daily or as directed by dentist or doctor.</p> <p>Children under 12 years of age: should be supervised in the use of this product.</p> <p>Children under 2 years of age: do not use.</p> <p>Other information Store at 59° to 86°F (15° to 30° C)</p> <p>Inactive ingredients Blue 1, Flavor, PEG-6, PEG-75, Red 3, Red 35, Red 40, sodium saccharin, Yellow 10* *contains one or more of these ingredients.</p> <p>Questions or comments? Centrix, Inc. 770 River Rd, Shelton, CT 06484 TEL: (203) 529-5382 TOLL FREE: (800) 235-5982 FAX: (203) 929-6904 www.centrixdental.com</p>

LolliCaine[®] CENTRIX

20% Benzocaine

TOPICAL ANESTHETIC GEL

REF 360092

120 Units
(0.4 g/0.3 mL per unit)



Mint 

59°F - 86°F (15°C - 30°C)



NDC: 60640-9200



LolliCaine[®] CENTRIX
20% Benzocaine

CONTAINS: 120 Units
(0.4 g/0.3 mL per unit)

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LOT



<p>Drug Facts</p> <p>Active ingredient (to each unit/dose/apply): Benzocaine 20%.....Oral Anesthetic</p> <p>Purpose Use 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</p> <p>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. Severe 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</p>	<p>Drug Facts (Contd...)</p> <p>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 right away.</p> <p>Directions 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</p> <p>Other information Store at 59° to 86° F (15° to 30° C)</p> <p>Inactive ingredients Blue 1*, flavor, PEG-3, PEG-75, Red 3*, Red 40*, sodium saccharin, Yellow 10* *contains one or more of these ingredients.</p> <p>Questions or comments? Contact: Centrix, Inc., 770 River Rd, Shelton, CT 06484 TEL: (203) 928-5382 TOLL FREE: (800) 235-5862 FAX: (203) 929-5804 www.centrixdental.com</p>
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LolliCaine[®] CENTRIX

20% Benzocaine

TOPICAL ANESTHETIC GEL

REF 360094

120 Units
(0.4 g/0.3 mL per unit)



Piña Colada



NDC: 60640-9400



LolliCaine[®] CENTRIX
20% Benzocaine

CONTAINS: 120 Units
(0.4 g/0.3 mL per unit)

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Drug Facts (Contd..) 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 right away. Directions 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 2 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 40*, sodium saccharin, Yellow 10* *contains one or more of these ingredients.	Drug Facts Active ingredient: (in each unit-dose pack) Benzocaine 20% Purpose Oral Anesthetic Use: For the temporary relief of occasional minor irritation and pain, associated with: • Sore mouth and throat • Minor dental procedures • Minor 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, butabaine, 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 sores/pain 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
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LolliCaine[®] CENTRIX

20% Benzocaine

INSTRUCTIONS FOR USE

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

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.

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.

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?

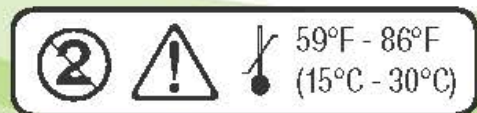
CENTRIX INCORPORATED

770 River Road, Shelton CT 06484 USA

Toll Free (USA): (800) 235-5862

Tel: (203) 929-5582 • Fax: (203) 929-6804

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LOLLICAINE BUBBLE GUM

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-8800
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	200 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
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:60640-8800-1	120 in 1 CARTON	01/14/2019	
1		0.4 g in 1 DOSE PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	01/14/2019		

LOLLICAINE CHERRY

benzocaine gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-9000
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	200 mg in 1 g
Inactive Ingredients			

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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:60640-9000-1	120 in 1 CARTON	01/14/2019	
1		0.4 g in 1 DOSE PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/14/2019	

LOLLICAINE MINT

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-9200
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

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:60640-9200-1	120 in 1 CARTON	01/14/2019	
1		0.4 g in 1 DOSE PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/14/2019	

LOLLICAINE PINA COLADA

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-9400
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor	COCONUT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60640-9400-1	120 in 1 CARTON	01/14/2019	
1		0.4 g in 1 DOSE PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/14/2019	

Labeler - Centrix, Inc. (053707303)

Revised: 1/2021

Centrix, Inc.