

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

LolliCaine is a flavored topical anesthetic gel featuring rapid onset, no systemic absorption and a 15 minute duration. LolliCaine is packaged in a 1-oz. jar.

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

Use appropriate 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. **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

www.centrixdental.com



LolliCaine[®]

20% Benzocaine



REF 310017

Contains: 1-oz. Jar

NDC 60640-1700-01



©2019 Centrix, Inc. | 000445 REV A

Drug Facts	Drug Facts (Contd..)
<p>Active ingredient (in each unit-dose pack)</p> <p>Benzocaine 20%.....</p> <p>Purpose</p> <p>Oral Anesthetic</p>	<p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>In case of overdose, get medical help or contact Poison Control Center right away.</p>
<p>Use For the temporary relief of occasional minor irritation and pain, associated with:</p> <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>Directions</p> <p>Use appropriate 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.</p> <p>Do not exceed recommended dosage.</p> <p>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.</p>
<p>Warnings</p> <p>For external use only</p> <p>Methemoglobinemia Warning</p> <p>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.</p> <p>Stop use and seek immediate medical attention if you or a child in your care develops:</p> <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>Other information</p> <p>Store at 59° to 86° F (15° to 30° C)</p>
<p>Allergy alert:</p> <p>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:</p> <p>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</p> <ul style="list-style-type: none"> • for teething • in children under 2 years of age 	<p>Inactive ingredients</p> <p>Blue 1*, flavor, PEG-8, PEG-75, Red 3*, Red 33*, Red 40*, sodium saccharin, Yellow 10*</p> <p>*contains one or more of these ingredients.</p> <p>Questions or comments?</p> <p>CENTRIX INCORPORATED 770 River Rd, Shelton, CT 06484 USA TEL: (203) 929-5582 TOLL FREE: (800) 235-5862 FAX: (203) 929-6804 www.centrixdental.com</p>
<p>When using this product</p> <p>avoid contact with eyes</p>	



LolliCaine®

20% Benzocaine



REF 310018

Contains: 1-oz. Jar

NDC 60640-1800-1



©2019 Centrix, Inc. | 000446 REV A

Drug Facts		Drug Facts (Contd..)	
Active ingredient (<i>in each unit-dose pack</i>)	Purpose	If pregnant or breast-feeding, ask a health professional before use.	
Benzocaine 20%.....	Oral Anesthetic	Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away.	
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		Directions Use appropriate 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. 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.	
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		Children under 12 years of age: should be supervised in the use of the product. Children under 2 years of age: do not use	
Allergy alert: Do not use if you have a history of allergy to any "caine" anesthetics, such as benzocaine, butacaine, procaine or tetracaine.		Other information Store at 59° to 86° F (15° to 30° C)	
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.		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.	
Do Not Use • for teething • in children under 2 years of age		Questions or comments? CENTRIX INCORPORATED 770 River Rd, Shelton, CT 06484 USA TEL: (203) 929-5582 TOLL FREE: (800) 235-5862 FAX: (203) 929-6804 www.centrixdental.com	
When using this product avoid contact with eyes			



LolliCaine®

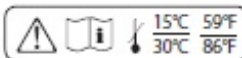
20% Benzocaine



REF 310019

Contains: 1-oz. Jar

NDC 60640-1900-1



©2019 Centrix, Inc. | 000447 REV A

Drug Facts		Drug Facts (Contd..)	
Active ingredient (<i>in each unit-dose pack</i>)	Purpose	If pregnant or breast-feeding, ask a health professional before use.	
Benzocaine 20%.....	Oral Anesthetic	Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away.	
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		Directions Use appropriate 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. 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.	
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		Children under 12 years of age: should be supervised in the use of the product. Children under 2 years of age: do not use	
Allergy alert: Do not use if you have a history of allergy to any "caine" anesthetics, such as benzocaine, butacaine, procaine or tetracaine.		Other information Store at 59° to 86° F (15° to 30° C)	
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.		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.	
Do Not Use • for teething • in children under 2 years of age		Questions or comments? CENTRIX INCORPORATED 770 River Rd, Shelton, CT 06484 USA TEL: (203) 929-5582 TOLL FREE: (800) 235-5862 FAX: (203) 929-6804 www.centrixdental.com	
When using this product avoid contact with eyes			



LolliCaine®

20% Benzocaine

pina colada  pina colada

REF 310020

Contains: 1-oz. Jar

NDC 60640-2000-1



©2019 Centrix, Inc. | 000448 REV A

Drug Facts		Drug Facts (Contd..)	
Active ingredient (in each unit-dose pack) Benzocaine 20%.....	PurposeOral Anesthetic	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.	
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		Directions Use appropriate 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. 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.	
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		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 Rd, Shelton, CT 06484 USA TEL: (203) 929-5582 TOLL FREE: (800) 235-5862 FAX: (203) 929-6804 www.centrixdental.com	

LOLLICAINE BUBBLE GUM

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-1700
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:60640-1700-1	1 in 1 CARTON	08/27/2019	
1		28.35 g in 1 JAR; 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	08/27/2019	

LOLLICAINE CHERRY

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-1800
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:60640-1800-1	1 in 1 CARTON	08/27/2019	
1		28.35 g in 1 JAR; 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	08/27/2019	

LOLLICAINE MINT

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-1900
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: HBR47K3TBD)	

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:60640-1900-1	1 in 1 CARTON	08/27/2019	
1		28.35 g in 1 JAR; 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	08/27/2019	

LOLLICAINE PINA COLADA

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60640-2000
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:60640-2000-1	1 in 1 CARTON	08/27/2019	
1		28.35 g in 1 JAR; 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	08/27/2019	

Labeler - Centrix, Inc. (053707303)**Establishment**

Name	Address	ID/FEI	Business Operations
Centrix, Inc.		053707303	repack(60640-1700, 60640-1800, 60640-1900, 60640-2000)

Revised: 1/2021

Centrix, Inc.