

**BENZOCAINE CHERRY- benzocaine gel**  
**BENZOCAINE MINT- benzocaine gel**  
**BENZOCAINE BUBBLE GUM- benzocaine gel**  
**BENZOCAINE STRAWBERRY- benzocaine gel**  
**BENZOCAINE RASPBERRY- benzocaine gel**  
**BENZOCAINE PINA COLADA- benzocaine gel**  
**Darby Dental Supply, LLC**

*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.*

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**20% Benzocaine Gel**

**Drug Facts**

**Active ingredients**

Benzocaine 200 mg (*in each g*)

**Purpose**

Oral Anesthetic

**Use**

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

**Warnings**

**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 the 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 on patients with a history of allergies to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

**Do not use**

- for more than 7 days unless directed by a physician. If sore mouth symptoms do not improve in 7 days; irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your physician promptly.
- for teething
- in children under 2 years of age

**When using this product**

Avoid contact with eyes. If contact occurs, flush with water.

**Do not exceed recommended dosage.** If more than used for pain is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**If pregnant or breast feeding,** ask a physician before use.

**Keep out of reach of children.**

**Directions**

- Apply only amount needed to the oral mucosa to prevent or relieve pain.
- children under 2 years of age: do not use

**Other information**

Store at 59° - 86°F (15 - 30°C). Protect from freezing.

**Inactive ingredients**

flavoring, PEG 3350, PEG 400, sodium saccharin, water. May contain blue #1, green #3, green #5, red #3, red #28, red #40, yellow #5, (tartrazine), yellow #6, as a color additive.

**Questions or comments?**

800-645-2310 or darby.com

**PRINCIPAL DISPLAY PANEL - 1 oz Jar Label - Cherry**

**DARBY®**

**DARBY DENTAL SUPPLY, LLC**

**20% Benzocaine Gel**

Topical Anesthetic Gel

Net Contents: 1 oz

DARBY

**QUALITY**

**CERTIFIED**

Manufactured for:

Darby Dental Supply, LLC

Jericho, NY 11753

**PEEL BACK** to review drug facts

PEEL BACK to review drug facts



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99093551 Rev 06/2018

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99093551 Rev 06/2018

benzocaine gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66467-4002
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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### 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:66467-4002-2	30 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/19/1963	

## BENZOCAINE MINT

benzocaine gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66467-4003
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<b>Route of Administration</b>	DENTAL
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### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-4003-2	30 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/19/1963	

## BENZOCAINE BUBBLE GUM

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66467-4001
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>Benzocaine</b> (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)		Benzocaine	220 mg in 1 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
WATER (UNII: 059QF0KO0R)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)				
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)				
D&C RED NO. 28 (UNII: 767IP0Y5NH)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
<b>Product Characteristics</b>				
<b>Color</b>	PINK		<b>Score</b>	
<b>Shape</b>			<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM		<b>Imprint Code</b>	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66467-4001-2	30 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part356	02/19/1963		

<b>BENZOCAINE STRAWBERRY</b>			
benzocaine gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66467-4006
<b>Route of Administration</b>	DENTAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)		Benzocaine	220 mg in 1 g
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>

WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-4006-2	30 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/19/1963	

## BENZOCAINE RASPBERRY

benzocaine gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66467-4000
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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

### Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-4000-2	30 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/19/1963	

## BENZOCAINE PINA COLADA

benzocaine gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66467-4004
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

### Product Characteristics

Color	WHITE (DYE FREE)	Score	
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<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COCONUT (Pina Colada)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-4004-2	30 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/19/1963	

**Labeler** - Darby Dental Supply, LLC (825137818)

**Registrant** - DSHealthcare (056296981)

**Establishment**

Name	Address	ID/FEI	Business Operations
Keystone Industries		014769301	MANUFACTURE(66467-4000, 66467-4001, 66467-4002, 66467-4003, 66467-4004, 66467-4006)