

BENZOCAINE MINT- benzocaine gel
BENZOCAINE BUBBLE GUM- 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.

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

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99093551 Rev 06/2018

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99093551 Rev 06/2018

BENZOCAINE MINT

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66467-4003
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	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

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	07/03/2023

BENZOCAINE BUBBLE GUM

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66467-4001
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: 059QF0K00R)	
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	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66467-4001-2	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	07/03/2023

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
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	white (DYE FREE)	Score	
Shape		Size	
Flavor	COCONUT (Pina Colada)	Imprint Code	
Contains			

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	07/03/2023

Labeler - Darby Dental Supply, LLC (825137818)

Registrant - DSHealthcare (056296981)

Establishment

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