

**KOLORZ TOPICAL ANESTHETIC TRIPLE MINT- benzocaine gel**  
**KOLORZ TOPICAL ANESTHETIC CHERRY BURST- benzocaine gel**  
**KOLORZ TOPICAL ANESTHETIC COTTON CANDY- benzocaine gel**  
**KOLORZ TOPICAL ANESTHETIC BLUE RASBERRY- benzocaine gel**  
**KOLORZ TOPICAL ANESTHETIC PINA COLADA- benzocaine gel**  
**DMG AMERICA, 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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**KOLORZ® TOPICAL ANESTHETIC**

**Drug Facts**

**Active ingredients (in each gram)**

Benzocaine 200 mg

**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 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 heartrate
- 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 benzocaine or other "caine" anesthetics.

## **Sore throat warning**

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, 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 contact occurs, flush with water.

**If pregnant or breast feeding**, consult a doctor before use.

**KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center immediately.

## **Directions**

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

## **Questions or comments?**

800-6626383 • [www.dmg-america.com](http://www.dmg-america.com)

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## **PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Triple Mint**

Best Taste...  
Guaranteed!

kolorz®

Topical Anesthetic Gel  
(Benzocaine 20%)

Triple Mint

1 FL OZ (29.6 grams)

\*D0337551010-\*



**INGREDIENTS:** Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. D&C Green #5. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

**NDC 25047-751-01**  
**RE-ORDER # 755101**

**EMERGENCY RESPONSE:**  
Call Infotrac 1-800-535-5053  
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Rev03/19

Best Taste...  
Guaranteed!



**Topical Anesthetic Gel**  
(Benzocaine 20%)

**Triple Mint**

1 FL OZ (29.6 grams)

### Drug Facts

#### Active ingredients (in each gram)

Benzocaine 200 mg

#### 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 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 heartrate
- 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 benzocaine or other "caine" anesthetics.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, 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 contact occurs, flush with water.

**If pregnant or breast feeding,** consult a doctor before use.

#### KEEP OUT OF REACH OF

**CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center immediately.

#### Directions

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

#### Questions or comments?

800-6626383 •  
www.dmg-america.com

**PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Cherry Burst**

Best Taste...  
Guaranteed!

kolorz<sup>®</sup>

Topical Anesthetic Gel  
(Benzocaine 20%)  
Cherry Burst

1 FL OZ (29.6 grams)

\*D0337551020.\*



**INGREDIENTS:** Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. FD&C Red #40. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

**NDC 25047-752-01**  
**RE-ORDER # 755102**

**EMERGENCY RESPONSE:**  
Call Infotrac 1-800-535-5053  
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**Best Taste...  
Guaranteed!**



**Topical Anesthetic Gel**  
(Benzocaine 20%)

**Cherry Burst**

**1 FL OZ (29.6 grams)**

**Drug Facts**

**Active ingredients  
(in each gram)**

Benzocaine 200 mg

**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 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 heartrate
- 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 benzocaine or other "caine" anesthetics.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, 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 contact occurs, flush with water.

**If pregnant or breast feeding,** consult a doctor before use.

**KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center immediately.

**Directions**

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

**Questions or comments?**

800-6626383 •  
www.dmg-america.com

**PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Cotton Candy**

Best Taste...  
Guaranteed!

kolorz®

Topical Anesthetic Gel  
(Benzocaine 20%)  
Cotton Candy

1 FL OZ (29.6 grams)



\*D0337551030\_\*



**INGREDIENTS:** Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. D&C Red #33. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

**NDC 25047-753-01**  
**RE-ORDER # 755103**

**EMERGENCY RESPONSE:**  
Call Infotrac 1-800-535-5053  
For professional use only.

**Best Taste...  
Guaranteed!**



**Topical Anesthetic Gel**  
(Benzocaine 20%)

**Cotton Candy** 1 FL OZ (29.6 grams)

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**Drug Facts**

**Active ingredients  
(in each gram)**

Benzocaine 200 mg

**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 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 heartrate
- 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 benzocaine or other "caine" anesthetics.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, 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 contact occurs, flush with water.

**If pregnant or breast feeding,** consult a doctor before use.

**KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center immediately.

**Directions**

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

**Questions or comments?**

800-6626383 •  
www.dmg-america.com

**PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Blue Raspberry**

Best Taste...



Guaranteed!

kolorz<sup>®</sup>

Topical Anesthetic Gel  
(Benzocaine 20%)  
Blue Raspberry

1 FL OZ (29.6 grams)

\*D0337551040\$\*



**INGREDIENTS:** Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. FD&C Blue #1. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

**NDC 25047-754-01**  
**RE-ORDER # 755104**

**EMERGENCY RESPONSE:**  
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Best Taste...  
Guaranteed!



**Topical Anesthetic Gel**  
(Benzocaine 20%)

**Blue Raspberry** 1 FL OZ (29.6 grams)

**Drug Facts**

**Active ingredients  
(in each gram)**

Benzocaine 200 mg

**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 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 heartrate
- 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 benzocaine or other "caine" anesthetics.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, 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 contact occurs, flush with water.

**If pregnant or breast feeding,** consult a doctor before use.

**KEEP OUT OF REACH OF**

**CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center immediately.

**Directions**

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

**Questions or comments?**

800-6626383 •  
www.dmg-america.com

**PRINCIPAL DISPLAY PANEL - 29.6 grams Bottle Label - Piña Colada**

Best Taste...

Guaranteed!

kolorz<sup>®</sup>

Topical Anesthetic Gel  
(Benzocaine 20%)  
Piña Colada

1 FL OZ (29.6 grams)

\*D0337551050/\*



**INGREDIENTS:** Each gram of Kolorz® Topical Anesthetic Gel contains 200mg of Benzocaine U.S.P., in a water soluble base. FD&C Yellow #5. Sweetened with Sucralose. Does not contain Aspartame or Saccharin. Gluten free.

**NDC 25047-755-01**  
**RE-ORDER # 755105**

**EMERGENCY RESPONSE:**  
Call Infotrac 1-800-535-5053  
For professional use only.

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Best Taste...  
Guaranteed!



**Topical Anesthetic Gel**  
(Benzocaine 20%)

**Piña Colada**

**1 FL OZ (29.6 grams)**

**Drug Facts**

**Active ingredients (in each gram)**

Benzocaine 200 mg

**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 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 heartrate
- 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 benzocaine or other "caine" anesthetics.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by

fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, 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 contact occurs, flush with water.

**If pregnant or breast feeding,** consult a doctor before use.

**KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical help or contact a Poison Control Center immediately.

**Directions**

- adults and children 2 years of age and older: 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, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5, FD&C Blue #1 as a color additive.

**Questions or comments?**

800-6626383 •  
www.dmg-america.com

**KOLORZ TOPICAL ANESTHETIC TRIPLE MINT**

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25047-751
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:25047-751-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

### Marketing Information

<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	09/06/2019	

## KOLORZ TOPICAL ANESTHETIC CHERRY BURST

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25047-752
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-752-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/06/2019	

**KOLORZ TOPICAL ANESTHETIC COTTON CANDY**

benzocaine gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25047-753
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	

**POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ)

**SUCRALOSE** (UNII: 96K6UQ3ZD4)

**D&C RED NO. 33** (UNII: 9DBA0SBB0L)

**FD&C RED NO. 40** (UNII: WZB9127XOA)

**D&C GREEN NO. 5** (UNII: 8J6RDU8L9X)

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

**FD&C BLUE NO. 1** (UNII: H3R47K3TBD)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-753-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/06/2019	

## KOLORZ TOPICAL ANESTHETIC BLUE RASBERRY

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25047-754
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	



## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-754-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/06/2019	

## KOLORZ TOPICAL ANESTHETIC PINA COLADA

benzocaine gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25047-755
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)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25047-755-01	29.6 g in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	09/06/2019	

**Labeler** - DMG AMERICA, LLC (106792427)

### Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	MANUFACTURE(25047-751, 25047-752, 25047-753, 25047-754, 25047-755) , PACK(25047-751, 25047-752, 25047-753, 25047-754, 25047-755) , LABEL(25047-751, 25047-752, 25047-753, 25047-754, 25047-755)

Revised: 10/2021

DMG AMERICA, LLC