

TOPEX PINA COLADA- benzocaine gel, dentifrice

TOPEX CHERRY- benzocaine gel, dentifrice

TOPEX MINT- benzocaine gel, dentifrice

TOPEX BUBBLE GUM- benzocaine gel, dentifrice

TOPEX STRAWBERRY- benzocaine gel, dentifrice

TOPEX RASPBERRY- benzocaine gel, dentifrice

Dentsply LLC. Professional Division Trading as "Sultan Healthcare"

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Topex[®] Topical Anesthetic Gel

20% Benzocaine

DIRECTIONS FOR USE

Gel - 1oz/30mL

AD31001 Cherry

AD31002 Mint

AD31004 Pina Colada

AD31005 Bubble-Num

AD31006 Strawberry

AD31007 Razzberry

Gel - 100g jar

AD31064 Cherry

AD31964 Mint

AD31067 Pina Colada

AD31068 Bubble-Num

For dental use only.

Rx only.

1. INDICATIONS AND USAGE

Indicated as a topical anesthetic for use on oral mucosa prior to local anesthetic injections, scaling and prophylaxis. Also useful to relieve discomfort associated with taking impressions and intraoral radiographs. Apply as required.

2. DOSAGE AND ADMINISTRATION

1. Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the bottle
2. Tightly re-cap the jar after each use.

3. DOSAGE FORMS AND STRENGTHS

Each gram of Topex Topical Anesthetic Gel contains between 180-220 mg benzocaine in

a flavored base.

4. CONTRAINDICATIONS

Do not use on individuals with a known sensitivity to benzocaine or PABA.

5. WARNINGS AND PRECAUTIONS

METHEMOGLOBINEMIA WARNING:

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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

Not for use in children under 2 years of age

Keep out of reach of children

For professional dental use only

Take care not to contaminate the jar by reintroducing a used cotton applicator into the jar

6. OVERDOSAGE

In case of overdose, get medical help or contact a Poison Control Center right away.

7. DESCRIPTION

Flavored 20% benzocaine gel or liquid for topical mucosal anesthesia.

8. HOW SUPPLIED / STORAGE AND HANDLING

Topex 20% benzocaine gel is supplied in multiple use containers.

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

MANUFACTURED FOR

Sultan Healthcare

1301 Smile Way • York, PA 17404 • USA

Toll Free: 800-637-8582 • Phone: 201-871-1232



Fax: 201-871-0321 • www.sultanhealthcare.com

Made in the USA
0031001DF, R4-072017



PRINCIPAL DISPLAY PANEL - Cherry 34 Gram

 Topex® Topical Anesthetic Gel Contains: 20% Benzocaine	 CHERRY	Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required. Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use. Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base. Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA. Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children. Overdose: In case of overdose, get medical help or contact a Poison Control Center right away. Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Cherry Flavor, Sodium Saccharin USP, Purified Water, Licorice Essence, FD&C Red #40 Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.		
		Net Contents: 1 oz (34g)	REF AD31001 NDC 0699-7021-34	Manufactured For: Sultan Healthcare 1301 Smile Way, York, PA 17404

PRINCIPAL DISPLAY PANEL - Mint 34 gram

 Topex® Topical Anesthetic Gel Contains: 20% Benzocaine	 MINT	Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required. Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use. Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base. Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA. Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children. Overdose: In case of overdose, get medical help or contact a Poison Control Center right away. Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Natural Peppermint Flavor, Purified Water, Licorice Essence, D&C Green #5 Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.		
		Net Contents: 1 oz (34g)	REF AD31002 NDC 0699-7011-34	Manufactured For: Sultan Healthcare 1301 Smile Way, York, PA 17404

PRINCIPAL DISPLAY PANEL - Pina Colada 34 gram

 Topex® Topical Anesthetic Gel Contains: 20% Benzocaine	 PINA COLADA	Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required. Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use. Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base. Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA. Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children. Overdose: In case of overdose, get medical help or contact a Poison Control Center right away. Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Pina Colada Flavor, Sodium Saccharin USP Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.		
		Net Contents: 1 oz (34g)	REF AD31004 NDC 0699-7001-34	Manufactured For: Sultan Healthcare 1301 Smile Way, York, PA 17404

PRINCIPAL DISPLAY PANEL - Bubble Num 34 gram



Topex®
Topical Anesthetic Gel

Contains: 20% Benzocaine



BUBBLE GUM

Rx only

Net Contents:
1 oz (34g)

REF AD31005
NDC 0699-7031-34

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

Toll Free: 800-637-8582
Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A.
0031025LA, Rev. 3 (0617)

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar.
Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Bubble Gum Flavor, Sodium Saccharin USP, Purified Water, D&C Red #28
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

PRINCIPAL DISPLAY PANEL - Strawberry 34 gram



Topex®
Topical Anesthetic Gel

Contains: 20% Benzocaine



STRAWBERRY

Rx only

Net Contents:
1 oz (34g)

REF AD31006
NDC 0699-7051-34

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

Toll Free: 800-637-8582
Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A.
0031026LA, Rev. 3 (0617)

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar.
Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Artificial Strawberry Flavor, Purified Water, FD&C Red #40
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

PRINCIPAL DISPLAY PANEL - Razzberry 34 gram



Topex®
Topical Anesthetic Gel

Contains: 20% Benzocaine



RAZZBERRY

Rx only

Net Contents:
1 oz (34g)

REF AD31007
NDC 0699-7061-34

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

Toll Free: 800-637-8582
Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A.
0031027LA, Rev. 3 (0617)

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar.
Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Artificial Raspberry Flavor, Purified Water, FD&C Red #40, D&C Red #28, FD&C Blue #1
Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

PRINCIPAL DISPLAY PANEL - Cherry 100 gram



Topex® Topical Anesthetic Gel

Contains: 20% Benzocaine



CHERRY

Rx only

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.

Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.

Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.

Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.

Warnings & Precautions: **METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.

Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.

Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Cherry Flavor, Sodium Saccharin USP, Purified Water, Licorice Essence, FD&C Red #40

Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

Net Contents:
100g

REF AD31064
NDC 0699-7071-01

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

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Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A
0031264LA, Rev. 3 (0617)

PRINCIPAL DISPLAY PANEL - Mint 100 gram



Topex® Topical Anesthetic Gel

Contains: 20% Benzocaine



MINT

Rx only

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.

Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.

Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.

Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.

Warnings & Precautions: **METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.

Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.

Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Sodium Saccharin USP, Natural Peppermint Flavor, Purified Water, Licorice Essence, D&C Green #5

Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

Net Contents:
100g

REF AD31065
NDC 0699-7081-01

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

Toll Free: 800-637-8582
Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A
0031265LA, Rev. 3 (0617)

PRINCIPAL DISPLAY PANEL - Pina Colada 100 gram



Topex® Topical Anesthetic Gel

Contains: 20% Benzocaine



PINA COLADA

Rx only

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.

Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.

Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.

Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.

Warnings & Precautions: **METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.

Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.

Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Pina Colada Flavor, Sodium Saccharin USP

Storage: Store between 59°-86°F (15°-30°C). Protect from freezing.

Net Contents:
100g

REF AD31067
NDC 0699-7091-01

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

Toll Free: 800-637-8582
Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A
0031267LA, Rev. 3 (0617)

PRINCIPAL DISPLAY PANEL - Bubble Num 100 gram



Topex® Topical Anesthetic Gel

Contains: 20% Benzocaine



Rx only

Net Contents:
100g

REF AD31068
NDC 0699-7100-01

Manufactured For:
Sultan Healthcare
1301 Smile Way, York, PA 17404

Toll Free: 800-637-8582
Phone: 201-871-1232
Fax: 201-871-0321

www.sultanhealthcare.com
Made in the U.S.A.
0031268LA, Rev. 3 (0617)

Indications & Usage: Indicated as a topical anesthetic for use on oral mucosa. Apply as required.
Dosage & Administration: Using a new cotton applicator, apply a small amount of gel to the mucosa to achieve topical anesthesia. Do not reintroduce the cotton applicator into the jar. Tightly re-cap the jar after each use.
Dosage Forms & Strength: Each gram contains between 180-220 mg benzocaine in a flavored base.
Contraindications: Do not use on individuals with a known sensitivity to benzocaine or PABA.
Warnings & Precautions: **METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient 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. Not for use in children under 2 years of age. Keep out of reach of children.
Overdosage: In case of overdose, get medical help or contact a Poison Control Center right away.
Ingredients: Benzocaine, Polyethylene Glycol 3350 NF, Polyethylene Glycol 400 NF, Artificial Bubble Gum Flavor, Sodium Saccharin USP, Purified Water, D&C Red #28
Storage: Store between 59°-86°F (15°-30° C). Protect from freezing.

TOPEX PINA COLADA

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7001
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	COCONUT (Pina Colada)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-7001-34	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	04/14/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	04/14/2023

TOPEX CHERRY

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7021
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KOOR)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

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:0699-7021-34	34 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
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX MINT

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7011
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
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

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:0699-7011-34	34 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
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX BUBBLE GUM

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7031
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
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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:0699-7031-34	34 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
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX STRAWBERRY

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7051
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Route of Administration	DENTAL
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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
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

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:0699-7051-34	34 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
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX RASPBERRY

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7061
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0K00R)	

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:0699-7061-34	34 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	09/11/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	09/11/2022

TOPEX CHERRY

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7071
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
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:0699-7071-01	100 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
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX MINT

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7081
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	

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:0699-7081-01	100 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
UNAPPROVED DRUG OTHER		02/19/1963	

TOPEX PINA COLADA

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7091
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
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	COCONUT (Pina Colada)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-7091-01	100 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	02/28/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	02/28/2019

TOPEX BUBBLE GUM

benzocaine gel, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-7100
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
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	

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:0699-7100-01	100 g in 1 JAR; Type 0: Not a Combination Product	02/19/1963	01/18/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/1963	01/18/2022

Labeler - Dentsply LLC. Professional Division Trading as "Sultan Healthcare" (167087753)

Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	MANUFACTURE(0699-7001, 0699-7011, 0699-7021, 0699-7031, 0699-7051, 0699-7061, 0699-7071, 0699-7081, 0699-7091, 0699-7100)

Revised: 12/2023

Dentsply LLC. Professional Division Trading as "Sultan Healthcare"