

**TOPEX 60 SECOND FLUORIDE GEL- sodium fluoride gel**  
**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.*

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**Topex APF Fluoride Gel**

**Indications & Usage**

For topical application to aid in the prevention of dental caries.

Treatment frequency should not exceed 4 treatments per year.

**Dosage & Administration**

1. DO NOT USE IF SEAL IS BROKEN. Shake well before using.
2. Fill applicator tray no more than 1/3 full with Fluoride gel.
3. Dry tooth surface and insert tray in mouth.
4. Use suction throughout treatment.
5. Have patient bite down for a minimum of 60 seconds to a maximum of 4 minutes. (A slight biting or chewing motion will provide interproximal coverage)
6. Remove tray and have patient expectorate excess gel. Do not swallow.
7. Instruct patient not to eat, drink, or rinse for 30 minutes after treatment.

**Dosage Forms & Strengths**

This topical gel contains 1.23% sodium fluoride ion.

**Contraindications**

Hypersensitivity to fluoride. Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**Warnings & Precautions**

- Do not swallow. Harmful if swallowed.
- Keep out of reach of children.
- May contain FD&C Yellow #5 or FD&C Yellow #6.
- This product is not intended for home or unsupervised consumer use.
- Safety and effectiveness below age 3 have not been

established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

**Adverse Reactions**

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticarial, gastric distress, headache, and weakness.

### **Overdosage**

If treatment dose is swallowed (less than 100 mg F), administer milk, limewater, or calcium-type antacid. In case of larger doses (1 pint contains 4.5 grams F ion, which is a lethal dose), use ipecac syrup emetic and immediately seek medical help.

### **Description**

Topex® Fluoride Gels are a family of topical fluoride gel products for professional application in trays.

### **Storage**

Store between 68° - 77°F (20° - 25°C). Do not allow to freeze.

### **Principal display panel - Cherry**

Rx Only

**INDICATIONS AND USAGE**

For topical application to aid in the prevention of dental caries. Treatment frequency should not exceed 4 treatments per year.

**DOSAGE AND ADMINISTRATION**

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2. Fill applicator tray no more than 1/3 full with Fluoride gel.
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6. Remove tray and have patient expectorate excess gel. **Do not swallow.**
7. Instruct patient not to eat, drink, or rinse for 30 minutes after treatment.

**DOSAGE FORMS AND STRENGTHS**

This topical gel contains 1.23% fluoride ion.

**CONTRAINDICATIONS**

Hypersensitivity to fluoride. Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**WARNINGS AND PRECAUTIONS**

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- Keep out of reach of children.
- This product is not intended for home or unsupervised consumer use.
- Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

**OVERDOSAGE**

If treatment dose is swallowed (less than 100 mg F), administer milk, limewater, or calcium-type antacid. In case of larger doses (1 pint contains 4.5 grams F ion, which is a lethal dose), use ipecac syrup emetic and immediately seek medical help.

**ADVERSE REACTIONS**

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticarial, gastric distress, headache, and weakness.

**INGREDIENTS**

Sodium Fluoride, Purified Water, Veegum D, Phosphoric Acid, Hydrofluoric Acid, Citric Acid, Xanthan Gum, Artificial Cherry Flavor, Xylitol, Tween 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, FD&C Red #40

**STORAGE**

Store between 50° - 77°F (10° - 25°C). Do not allow to freeze.

Made in USA Consult [www.sultanhealthcare.com](http://www.sultanhealthcare.com) for SDS and DFU

0031121SC, Rev7/062017

NDC 0699-0311-16  
REF AD31111

# Topex<sup>®</sup> 60 Second FLUORIDE GEL Cherry



**THIXOTROPIC**

Acidulated Phosphated Fluoride

Contains: 2.59% Sodium Fluoride (1.23% Fluoride Ion)

**Rx Only**



Warning: Causes skin irritation.  
Causes severe eye irritation.

Manufactured by: Sultan Healthcare  
1301 Smile Way • York, PA 17404 • USA  
Toll Free: 800-837-8582 • Phone: 201-871-1232  
Fax: 201-871-0321 • [www.sultanhealthcare.com](http://www.sultanhealthcare.com)



**Sultan Healthcare**

**CONTENTS: 16 FL OZ. (498 g)**

2.75 X 1  
2D BARCODE  
AREA

Principal Display Label - Mint

**INDICATIONS AND USAGE**

For topical application to aid in the prevention of dental caries. Treatment frequency should not exceed 4 treatments per year.

**DOSE AND ADMINISTRATION**

- DO NOT USE IF SEAL IS BROKEN. Shake well before using.
- Fill applicator tray no more than 1/3 full with Fluoride gel.
- Dry tooth surface and insert tray in mouth.
- Use suction throughout treatment.
- Have patient bite down for a minimum of 60 seconds to a maximum of 4 minutes. (A slight biting or chewing motion will provide interproximal coverage)
- Remove tray and have patient expectorate excess gel. **Do not swallow.**
- Instruct patient not to eat, drink, or rinse for 30 minutes after treatment.

**DOSE FORMS AND STRENGTHS**

This topical gel contains 1.23% fluoride ion.

**CONTRAINDICATIONS**

Hypersensitivity to fluoride. Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**WARNINGS AND PRECAUTIONS**

- Do not swallow. Harmful if swallowed.
- Keep out of reach of children.
- Contains FD&C Yellow #5
- This product is not intended for home or unsupervised consumer use.
- Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

**OVERDOSAGE**

If treatment dose is swallowed (less than 100 mg F), administer milk, lime water, or calcium-type antacid. In case of larger doses (1 pint contains 4.5 grams F ion, which is a lethal dose), use ipecac syrup emetic and immediately seek medical help.

**ADVERSE REACTIONS**

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticarial, gastric distress, headache, and weakness.

**INGREDIENTS**

Sodium Fluoride, Purified Water, Veegum D, Phosphoric Acid, Hydrofluoric Acid, Citric Acid, Xanthan Gum, Natural Mint Flavor, Xylitol, Titanium Dioxide, Tween 20, Sodium Benzoate, Sodium Saccharin, FD&C Blue #1, FD&C Yellow #5

**STORAGE**

Store between 50° - 77°F (10° - 25°C). Do not allow to freeze.

Made in USA Consult [www.sultanhealthcare.com](http://www.sultanhealthcare.com) for SDS and DFU

00311225C, R6-062017

NDC 0699-0312-16  
REF AD31112

# Topex<sup>®</sup> 60 Second FLUORIDE GEL

Mint 

**THIXOTROPIC**

Acidulated Phosphated Fluoride

Contains: 2.59% Sodium Fluoride (1.23% Fluoride Ion)

**Rx Only**



**Warning: Causes skin irritation.  
Causes severe eye irritation.**

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2.75 X 1  
2D BARCODE  
AREA

Sultan

**Sultan Healthcare**

**CONTENTS: 16 FL OZ. (498 g)**

**Principal Display Label - Orange Cream**

**INDICATIONS AND USAGE**

For topical application to aid in the prevention of dental caries. Treatment frequency should not exceed 4 treatments per year.

**DOSAGE AND ADMINISTRATION**

- DO NOT USE IF SEAL IS BROKEN. Shake well before using.
- Fill applicator tray no more than 1/3 full with Fluoride gel.
- Dry tooth surface and insert tray in mouth.
- Use suction throughout treatment.
- Have patient bite down for a minimum of 60 seconds to a maximum of 4 minutes. (A slight biting or chewing motion will provide interproximal coverage)
- Remove tray and have patient expectorate excess gel. **Do not swallow.**
- Instruct patient not to eat, drink, or rinse for 30 minutes after treatment.

**DOSAGE FORMS AND STRENGTHS**

This topical gel contains 1.23% fluoride ion.

**CONTRAINDICATIONS**

Hypersensitivity to fluoride. Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

**WARNINGS AND PRECAUTIONS**

- Do not swallow. Harmful if swallowed.
- Keep out of reach of children.
- Contains FD&C Yellow #6.
- This product is not intended for home or unsupervised consumer use.
- Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential. Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

**OVERDOSAGE**

If treatment dose is swallowed (less than 100 mg F), administer milk, lime water, or calcium-type antacid. In case of larger doses (1 pint contains 4.5 grams F ion, which is a lethal dose), use ipecac syrup emetic and immediately seek medical help.

**ADVERSE REACTIONS**

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticarial, gastric distress, headache, and weakness.

**INGREDIENTS**

Sodium Fluoride, Purified Water, Veegum D, Phosphoric Acid, Hydrofluoric Acid, Citric Acid, Xanthan Gum, Artificial and Natural Tangerine Flavor, Xylitol, Tween 20, Sodium Benzoate, Sodium Saccharin, Titanium Dioxide, FD&C Yellow #6

**STORAGE**

Store between 50° - 77°F (10° - 25°C). Do not allow to freeze. Made in USA. Consult [www.sultanhealthcare.com](http://www.sultanhealthcare.com) for SDS and DFU

**Rx Only**

NDC 0699-0317-16  
REF AD31117

**Topex<sup>®</sup>**  
**60 Second**  
FLUORIDE GEL

Orange Cream 

**THIXOTROPIC**

Acidulated Phosphated Fluoride

Contains: 2.59% Sodium Fluoride (1.23% Fluoride Ion)

**Rx Only**

00311ZTSC, RT-062017



Warning: Causes skin irritation.  
Causes severe eye irritation.

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**Sultan****Sultan Healthcare****CONTENTS: 16 FL OZ. (498 g)**

2.75 X 1  
2D BARCODE  
AREA

**TOPEX 60 SECOND FLUORIDE GEL**

sodium fluoride gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0699-0317
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

POLYSORBATE 20 (UNII: 7T1F30V5YH)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
XYLITOL (UNII: VCQ006KQ1E)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PHOSPHORIC ACID (UNII: E4GA8884NN)
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
XANTHAN GUM (UNII: TTV12P4NEE)
WATER (UNII: 059QF0K00R)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
TANGERINE (UNII: KH3E3096OO)

### Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	ORANGE (Orange Cream)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0317-16	498 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

## TOPEX 60 SECOND FLUORIDE GEL

sodium fluoride gel

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-0311
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### 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:0699-0311-16	498 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

## TOPEX 60 SECOND FLUORIDE GEL

sodium fluoride gel

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-0312
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYZQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	25.9 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROFLUORIC ACID (UNII: RGL5YE86CZ)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SPEARMINT (UNII: J7I2T6IV1N)	

## 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:0699-0312-16	498 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1900	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1900	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	manufacture(0699-0311, 0699-0312, 0699-0317)

Revised: 10/2017

Dentsply LLC. Professional Division Trading as "Sultan Healthcare"