

TOPEX NEUTRAL PH FLUORIDE GEL STRAWBERRY- sodium fluoride gel
TOPEX NEUTRAL PH FLUORIDE GEL MINT- 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.

Topex Neutal pH
Neutral Sodium Fluoride Gel

INDICATIONS AND USAGE

Topex® Fluoride Gels are indicated for topical application to teeth to aid in the prevention of dental caries.

The non-acidic nature of Neutral pH (NaF) is recommended for patients with ceramic or composite restorations.

Treatment frequency should not exceed 4 treatments per year.

DOSAGE AND ADMINISTRATION

1. Remove cap from bottle, remove induction seal. DO NOT USE IF SEAL IS BROKEN.
2. Replace cap and shake well.
3. Fill applicator tray no more than 1/3 full with Fluoride gel.
4. Dry tooth surface and insert tray in mouth.
5. Use suction throughout treatment.
6. 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)
7. Remove tray and have patient expectorate excess gel. Do not swallow.
8. Instruct patient not to eat, drink, or rinse for 30 minutes after treatment.

DOSAGE FORMS AND STRENGTHS

APF topical gel contains 2.59% sodium fluoride (1.23% fluoride ion).

NaF topical gel contains 2.0% sodium fluoride (0.9% 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.

May contain FD&C Yellow #5 & 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 AND HANDLING

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

PRINCIPAL DISPLAY PANEL - 480 mL Bottle Label

NDC 0699-0701-16

REF AD31130

Topex®

NEUTRAL pH

NEUTRAL SODIUM FLUORIDE GEL

Mint

Contains 2.0% Sodium Fluoride

(0.9% Fluoride Ion)

Rx Only

Sultan®

SultanHealthcare

CONTENTS: 16 FL OZ. (480mL)

INDICATIONS AND USAGE Rx only
For topical application to aid in the prevention of dental caries. The non-acidic nature of Neutral pH is recommended for patients with ceramic or composite restorations. 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 2.0% sodium fluoride (0.9% 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.
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INGREDIENTS
Sodium Fluoride, Purified water, Carbopol 974 PNF/Carbomer Homopolymer Type B, Xanthan Gum, Disodium Phosphate, Anhydrous, Sodium Hydroxide, Artificial Mint Flavor, Benzoic Acid, Sodium Saccharin, Green Solution (D&C Yellow #10/FD&C Blue#1), Methyl Paraben

STORAGE
Store between 68° - 77°F (20° - 25°C). Do not allow to freeze.
Made in USA Consult www.sultanhealthcare.com for SDS and DFU

NDC 0699-0701-16
REF AD31130


Topex[®]
NEUTRAL pH
NEUTRAL SODIUM FLUORIDE GEL
Mint 

Contains 2.0% Sodium Fluoride
(0.9% Fluoride Ion)
R Only

00311301A Rev:5-102019

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

2.75 X 1
2D BARCODE
AREA

 **SultanHealthcare**
CONTENTS: 16 FL OZ. (480mL)

PRINCIPAL DISPLAY PANEL - Clearly Strawberry 16 oz bottle

INDICATIONS AND USAGE

Rx only

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DOSAGE AND ADMINISTRATION

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INGREDIENTS

Sodium Fluoride, Purified water, Carbopol 974 PNF/Carbomer Homopolymer Type B, Xanthan Gum, Disodium Phosphate, Anhydrous, Sodium Hydroxide, Artificial Strawberry Flavor, Benzoic Acid, Sodium Saccharin, Methyl Paraben

STORAGE

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

Made in USA Consult www.sultanhealthcare.com for SDS and DRU

Manufactured for: Sultan Healthcare
1303 Smile Way • York, PA 17404 • USA
Toll Free: 800-697-8582 • Phone: 203-973-1252
Fax: 203-973-0923 • www.sultanhealthcare.com

2.75 X 1
2D BARCODE
AREA

UNVARNISHED

NDC 0699-0702-16
REF AD31132

Topex
NEUTRAL pH
NEUTRAL SODIUM FLUORIDE GEL
Clearly Strawberry 

Contains 2.0% Sodium Fluoride
(0.9% Fluoride Ion)

Rx Only

 **Sultan Healthcare**

CONTENTS: 16 FL OZ (480mL)

TOPEX NEUTRAL PH FLUORIDE GEL STRAWBERRY

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-0702
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUORIDE ION (UNII: Q80VPU4080) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	9 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0702-16	495 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1974	08/18/2023

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1974	08/18/2023

TOPEX NEUTRAL PH FLUORIDE GEL MINT

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-0701
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FLUORIDE ION (UNII: Q80VPU4080) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	9 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII:	

HHT01Z NK31)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

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:0699-0701-16	495 g in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1974	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1974	

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

Establishment

Name	Address	ID/FEI	Business Operations
Dentsply Caulk		083235549	MANUFACTURE(0699-0701, 0699-0702)

Revised: 1/2022

Dentsply LLC. Professional Division Trading as "Sultan Healthcare"