

EVERSMILE ALIGNERFRESH ENAMEL GUARD- sodium fluoride rinse
Everbrands, Inc.

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.

ALIGNERFRESH ENAMEL GUARD FLUORIDE FOAM

DRUG FACTS

Purpose

Anticavity

Active ingredient

Sodium fluoride 0.05%

(0.0225% w/v fluoride ion)

Uses

- aids in prevention of dental cavities

Warnings

Stop use and ask a dentist if oral irritation or tooth sensitivity occurs

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a poison Control Center right away.

Directions:

Tray application

- Adults and children 12 yrs. of age and older:
- Dispense up to a full pump of foam inside each tray.
- Use the nozzle tip to cover all areas of the tray evenly with foam.
- Place form-filled trays back in mouth.
- Spit out excess.
- No need to rinse as foam naturally dissipates.
- Do not swallow rinse.
- Children under 12 years of age: consult a dentist or doctor.

To rinse:

- Adults and children 12 years & older:
- Use twice a day after brushing your teeth with a toothpaste.
- Vigorously swish 2 pumps of rinse between your teeth for 1 minute and then spit out.
- Do not swallow the rinse.
- Do not eat or drink for 30 minutes after rinsing.
- Instruct children under 12 years of age in good rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.

- Children under 12 years of age: consult a dentist or doctor.

Other Information store at controlled room temperature 68-77°F (20 - 25°C)

Inactive Ingredients:

Etidronic Acid, glycerin, hydrogen peroxide, menthe arvensis oil, PEG, PVP, sodium benzoate, sodium citrate, sodium lauryl sulfate. sucralose, water

Questions? +1 (855) 595-2999

Package Label

EverSmile®

ALIGNERFRESH

ENAMEL

GUARD

FLUORIDE FOAM

50 mL (1.69fl oz)

Manufactured By
EverBrands, Inc. 401 N Oak St.
Inglewood, CA 90302

855 595-2999

info@eversmilewhite.com

www.eversmilewhite.com

EverSmile®

EverSmile®

ALIGNERFRESH

ENAMEL
GUARD

FLUORIDE FOAM



50ml (1.69 fl.oz.)



Vegan



Sugar Free



Gluten Free



Dairy Free



Whitens Teeth



Anti Cavity



Protects Against
Gingivitis



Freshens Breath

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.05%	Anticavity

Uses
• aids in prevention of dental caries

Warnings
Always use as directed. If oral irritation or tooth sensitivity occurs, keep out of reach of children. If more than used for 10 days, or if accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions:
To use:
• Adults and children 12 years of age and older:
• Dispense onto a flat, pump of foam inside each tray.
• Use the nozzle tip to cover all areas of the tray evenly with foam.
• Place foam filled tray back in mouth.
• Spit out excess.
• Do not swallow foam.
• Do not swallow the foam.
• Children under 12 years of age, consult a dentist or doctor.

To use:
• Adults and children 12 years of age and older:
• Use twice a day after brushing your teeth with a toothpaste.
• Vigorously swirl 2 pumps of foam between your teeth for 1 minute and then spit out.
• Do not swallow the foam.
• Do not eat or drink for 30 minutes after using.
• Children under 12 years of age: If good brushing habits do not help with staining, separate children as necessary until capable of using without supervision.
• Children under 12 years of age, consult a dentist or doctor.

Other Information
Store at controlled room temperature 68°-77°F (20°-25°C)

Inactive Ingredients:
Sodium acid phosphate, hydrogen peroxide, menthyl urea, oil of mint, PVP, sodium benzoate, sodium citrate, sodium lauryl sulfate, saccharin, water

Questions? +1 (855) 595-2999

Compatibility
• Invisalign®
• SmileDirectClub®
• ClearChoice®
• Byte®
• Straight Smile, LLC
• iSmile Remainers
• Vivant® Retainers
• Hawley Retainers

May discolor clear methyl methacrylate appliances. Ask your dentist.

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Manufactured By: **EverSmile, Inc.** 855-595-2999
10000 S. 10th St. Suite 1000, Scottsdale, AZ 85260
info@eversmile.com
eversmile.com



Strengthens & protects
with fluoride

ORTHODONTIST
RECOMMENDED

Made Specifically
For Aligner &
Retainer Wearers

Simple Foam
Application



foaming bubbles

fresh mint



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Please Recycle Me!

Drug Facts

Active ingredient	Purpose
Sodium fluoride 0.05% (0.0225% w/v fluoride ion)	Anticavity

Uses
+ aids in prevention of dental cavities

Warnings
Stop use and ask dentist if oral irritation or tooth sensitivity occurs.
Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions:
Tray application
> Adults and children 12 yrs. of age and older:
> Dispense up to a full pump of foam inside each tray.
> Use the nozzle tip to cover all areas of the tray evenly with foam.
> Place foam-filled trays back in mouth.
> Spit out excess.
> No need to rinse as foam naturally dissipates.
> Do not swallow the rinse.
> Children under 12 years of age: consult a dentist or doctor.

Drug Facts (continued)

Directions: (continued)
For rinse:
> Adults and children 12 years & older:
> Use twice a day after brushing your teeth with toothpaste.
> Vigorously swish 2 pumps of rinse between your teeth for 1 minute and then spit out.
> Do not swallow the rinse.
> Do not eat or drink for 30 minutes after rinsing.
> Instruct children under 12 years of age in good rinsing habits (to minimize swallowing).
> Supervise children as necessary until capable of using without supervision.
> Children under 12 years of age: consult a dentist or doctor.

Other Information
Store at controlled room temperature 68-77°F (20-25°C)

Inactive Ingredients:
Etidronic acid, glycerine, hydrogen peroxide, mentha arvensis oil, PEG, PVP, sodium benzoate, sodium citrate, sodium lauryl sulfate, sucralose, water

Questions? +1 (855) 595-2999

50 ml (1.69 fl oz)

EverSmile
ALIGNERFRESH
ENAMEL GUARD
FLUORIDE FOAM
Strengthens & protects with fluoride

res

EVERSMILE ALIGNERFRESH ENAMEL GUARD

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72655-300
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.225 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ETIDRONIC ACID (UNII: M2F465ROXU)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
MENTHA ARVENSIIS FLOWER OIL (UNII: Q129Z1W6Y2)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72655-300-01	1 in 1 PACKAGE	02/16/2022	
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/16/2022	

Labeler - Everbrands, Inc. (080314845)

Registrant - Everbrands, Inc. (080314845)

Establishment			
Name	Address	ID/FEI	Business Operations
Everbrands, Inc.		080314845	manufacture(72655-300)

Revised: 3/2022

Everbrands, Inc.