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

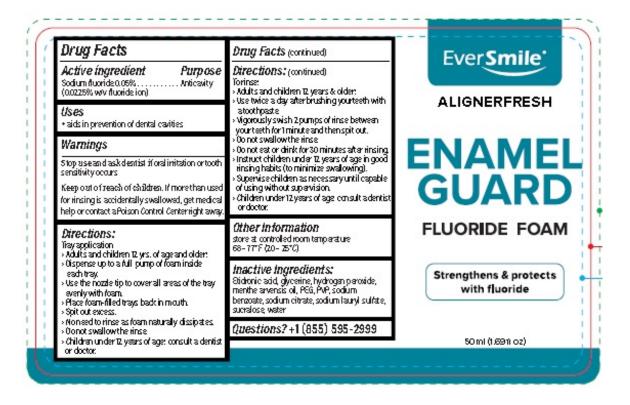
FLUORIDE FOAM

50 mL (1.69fl oz)

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

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EVERSMILE ALIGNER	RFRESH ENAME	L GUARD			
sodium fluoride rinse					
Product Information					
Product Type	HUMAN OTC DRUG Item Code (Source)		ND	NDC:72655-300	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name			Basis of Strength		Strength
SODIUM FLUORIDE (UNII: 8ZYQ1- UNII:Q80VPU4080)		FLUORIDE ION		0.225 mg in 1 mL	
Inactive Ingredients					
Ingredient Name					Strength
ETIDRONIC ACID (UNII: M2F465RC					
GLYCERIN (UNII: PDC6A3C0OX)					
HYDROGEN PEROXIDE (UNII: BBX					
MENTHA ARVENSIS FLOWER OI	_ (UNII: Q129Z1W6Y2)				
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)				
POVIDONE K30 (UNII: U725QWY32					
SODIUM BENZOATE (UNII: OJ245FE5EU)					
SODIUM CITRATE (UNII: 1Q73Q2)	JLR)				
SODIUM LAURYL SULFATE (UNII:	368GB5141J)				

SUCRALOSE (UNI								
WATER (UNII: 059								
Product Chai	racteristics							
Color Score								
Shape			Size					
Flavor		MINT	Imprint Code					
Contains								
Packaging								
# Item Code	Pac	Package Description		Marketing Start Date	Marketing End Date			
1 NDC:72655- 300-01	1 in 1 PACKAGE	1 PACKAGE		02/16/2022				
1	50 mL in 1 BOTT Combination Proc	LE, PUMP; Type 0: duct	Not a					
Marketing	Information	on						
Marketing Category	Applicati	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date			
OTC monograph n final	ot part356			02/16/2022				
iniui								

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.