

SMILEBAR WHITENING- sodium fluoride paste, dentifrice

Smilebar

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.

SMILEBAR WHITENING TOOTHPASTE WITH FLUORIDE + BAKING SODA

Drug facts

Active ingredient

Sodium Fluoride 0.243%

Purpose

Anticavity

Uses

Helps protect against cavities

Warnings: Keep out of reach of children under 6 yrs. of age.

If large amount (more than would be used for brushing) is swallowed, get medical help, or contact a Poison Control Center right away.

Directions

- Brush teeth thoroughly after
meals or at least two times a day
(or use as directed by a dentist)
- Do not swallow
- Not for children under 6

Inactive ingredients: Glycerin, Water,
Hydrated Silica, Sodium Lauryl Sulfate,
Sodium Bicarbonate, PEG, CMC, Sodium
Saccharin, Zinc Citrate, Flavor, Sucralose,
Titanium Dioxide, Tri-calcium Phosphate

Package Labeling

**WHITENING TOOTHPASTE
WITH FLUORIDE + BAKING SODA
DESIGNED FOR CLEAR ALIGNER TREATMENT**

**WHITENS PROTECTS GUMS
FIGHTS CAVITIES RESTORES ENAMEL**

NET WT 3.4 OZ e96 G

**WHITENS TEETH BY REMOVING
SURFACE STAINS, TARTER, AND PLAQUE**

SMILEBAR.COM

Distributed by SMILEBAR

303 Columbus Ave

Boston, MA 02116

WHITENING TOOTHPASTE
WITH FLUORIDE + BAKING SODA

SMILEBAR

DESIGNED FOR
CLEAR ALIGNER TREATMENT

WHITENS PROTECTS GUMS
FIGHTS CAVITIES RESTORES ENAMEL

NET WT 3.4OZ e96G

WHITENS TEETH BY REMOVING
SURFACE STAINS, TARTAR, AND PLAQUE.

Directions

- Brush teeth thoroughly after meals or at least two times a day (or use as directed by a dentist)
- Do not swallow
- Not for children under 6



Use: Helps protect against cavities

Drug facts

Active ingredient	Purpose
Sodium Fluoride 0.243%	Anticavity

Inactive Ingredients: Glycerin, Water, Hydrated Silica, Sodium Lauryl Sulfate, Sodium Bicarbonate, PEG, CMC, Sodium Saccharin, Zinc Citrate, Flavor, Sucralose, Titanium Dioxide, Tri-Calcium Phosphate

SMILEBAR.COM

Warning: Keep out of reach of children under 6 yrs. of age. If large amount (more than would be used for brushing) is swallowed, get medical help, or contact a Poison Control Center right away.

Distributed by SMILEBAR
303 Columbus Ave
Boston, MA 02116

res

SMILEBAR WHITENING

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73449-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	2.43 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ZINC CITRATE (UNII: K72I3DEX9B)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73449-001-01	96 g in 1 TUBE; Type 0: Not a Combination Product	11/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/15/2019	

Labeler - Smilebar (065798164)**Registrant** - Smilebar (065798164)

Revised: 12/2020

Smilebar