

AURAGLOW DAILY- sodium fluoride paste, dentifrice
Auraglow LLC

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.

Auraglow Daily Toothpaste

Drug Facts

Active ingredient

Sodium fluoride 0.243%
(0.15% w/v fluoride ion)

Purpose Anticavity

Use Aids in prevention of dental cavities.

Warnings

Keep out of reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older:
Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). • Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients

Deionized water, sorbitol, hydrated silica, xylitol, glycerin, polyethylene glycol, sodium methyl cocoyl taurate, flavor, cellulose gum, dimethicone, monosodium phosphate, stevia, sodium benzoate

Package Labeling

Auraglow

Daily

Toothpaste

Strengthens Teeth

and prevents cavities.

Wintergreen

CONTAINS FLUORIDE

NET WT 4.0 OZ (113G)

Distr. by Auraglow LLC, Stamford, CT 06901



Auraglow

Daily Toothpaste

Strengthens teeth
and prevents cavities.

Wintergreen
CONTAINS FLUORIDE

NET WT 4.0 OZ (113G)

Give your smile everything it needs to be its healthiest with toothpaste that strengthens the teeth while preventing cavities.



Cavity
Prevention



Strengthens
Teeth

Drug Facts	
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Directions • Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. • Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). • Supervise children as necessary until capable of using without supervision. • Children under 2 years of age: Consult a dentist or doctor.	
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AURAGLOW DAILY			
sodium fluoride paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81740-002
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)		SODIUM FLUORIDE	2.43 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81740-002-01	1 in 1 CARTON	08/01/2021	
1		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/01/2021	

Labeler - Auraglow LLC (066094893)

Registrant - Auraglow LLC (066094893)