# **AURAGLOW WHITENING-** 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.

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#### **Auraglow Whitening 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 thouroughly, 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

Sorbitol, hydrated silica, deionized water, glycerin, hydrogen peroxide, polyethylene glycol, sodium tripolyphosphate, cellulose gum, sodium methyl cocoyl tautate, flavor, stevia, sodium bicarbonate

# Package Labeling Auraglow

Whitening Toothpaste

Wintergreen

# CONTAINS FLUORIDE & 3% HYDROGEN PEROXIDE NET WT 4.0 OZ (113G)

Distr. by Auraglow LLC, Stamford, CT 06901





Upgrade your oral care routine with toothpaste that whitens the teeth while preventing cavities.





Cavity Prevention

Whitens Teeth

#### **Drug Facts**

#### Active Ingredient Sodium fluoride 0.243%

Purpose

(0.15% w/v fluoride ion)

#### Uses

Aids in prevention of dental cavities

#### Warning

Keep out of reach of children under 6 years of age. If more than used for brushing is accidently 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.

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#### **AURAGLOW WHITENING**

sodium fluoride paste, dentifrice

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81740-001

**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

SORBITOL (UNII: 506T60A25R)

HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:81740-001- 01	1 in 1 CARTON	07/01/2021			
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	07/01/2021		

## Labeler - Auraglow LLC (066094893)

## Registrant - Auraglow LLC (066094893)

Revised: 11/2022 Auraglow LLC