PLAQUE HD ANTICAVITY FRESH MINT FLAVOR PROFESSIONAL PLAQUE-IDENTIFYING- sodium fluoride paste, dentifrice
TJA Health LLC

PLAQUE HD ANTICAVITY TOOTHPASTE FRESH MINT FLAVOR

Drug Facts

Active Ingredient

Sodium Fluoride 0.24% (0.14% w/v Fluoride Ion)

Purpose

Anticavity

Use

Aids in the 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 or older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a 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 year of age: Consult a dentist or doctor

Other information

- Store at room temperature

Inactive ingredients

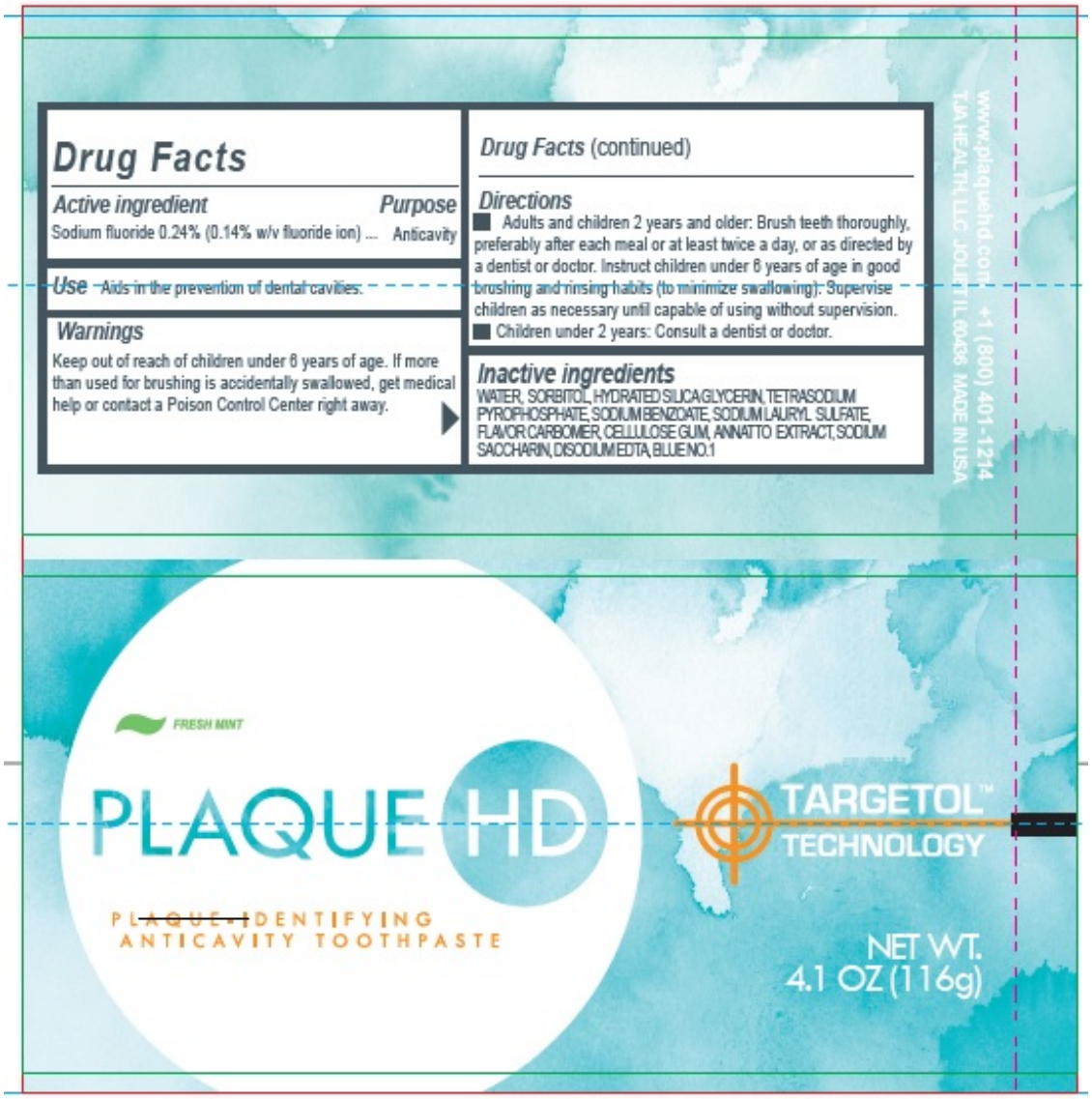
Water, sorbitol, hydrated silica, glycerin, tetrasodium pyrophsphate, sodium bicarbonate, PVP, sodium benzoate, sodium lauryl sulfate, flavor, carbomer, cellulose gum, annatto extract, xylitol, sodium saccharin, disodium EDTA, blue 1.

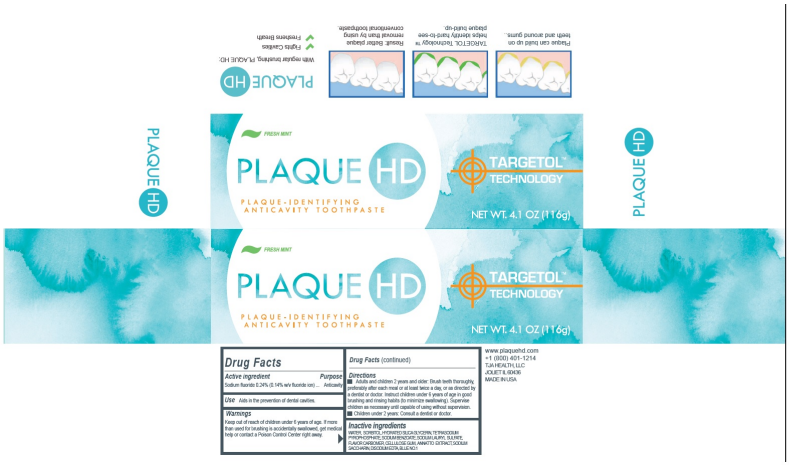
Questions?

call toll-free-1-(800) 737-4860

Package Labeling: 57660-000-01

Representative Labeling (57660-000-03)





PLAQUE HD ANTICAVITY FRESH MINT FLAVOR PROFESSIONAL PLAQUE-IDENTIFYING

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57660-000
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.14 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
ANNATTO (UNII: 6PQP1V1B6O)	
XYLITOL (UNII: VCQ006KQ1E)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT (Fresh Mint Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57660-000-01	1 in 1 PACKAGE	06/10/2013	
1		116 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:57660-000-02	1 in 1 PACKAGE	06/10/2013	
2		21 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:57660-000-03	1 in 1 PACKAGE	06/10/2013	
3		116 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 Drug	M021	06/10/2013	

Labeler - TJA Health LLC (078799634)

Registrant - TJA Health LLC (078799634)

Establishment

Name	Address	ID/FEI	Business Operations
TJA Health LLC		078799634	manufacture(57660-000)

Revised: 12/2023 TJA Health LLC