PLAQUE HD ANTICAVITY BERRY BUBBLE GUM FLAVOR PROFESSIONAL PLAQUE-IDENTIFYING- sodium fluoride paste, dentifrice TIA Health LLC

PLAQUE HD ANTICAVITY TOOTHPASTE BERRY BUBBLE GUM 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

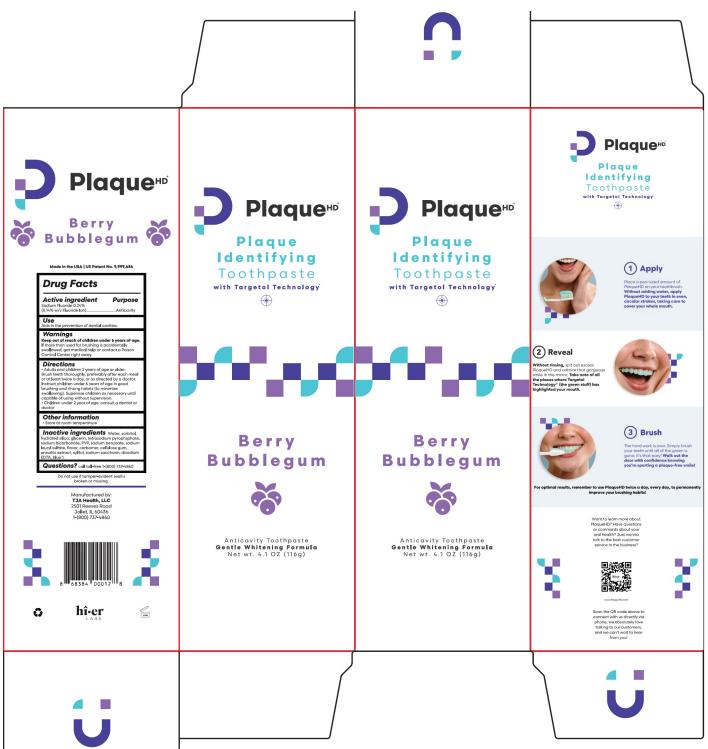
Inactive ingredients

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 (57660-001-01)





Representative Labeling (57660-001-02)























NET WT. 4.1 OZ (116g)

Drug Facts

Drug Facts (continued)

Inactive ingredients
WHER SORBITOL HYDRATED SUCAGLYCERN, TETRASODUM
PYROPHOSPHATE SODUM BENZOATE, SODUM LALARYL SULFATE
FAUROCARBONER CELLULOSE SOM, ANNATTO EXTRACT, SODU
SACCHARIN, DISCOLIMENTA, BLUE NO.1

www.plaquehd.com +1 (800) 401-1214 TJA HEALTH, LLC JOLIET IL 60436 MADE IN USA

Active ingredient Purpose
Sodium fluoride 0.24% (0.14% w/v fluoride ion) ... Anticavity

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PLAQUE HD ANTICAVITY BERRY BUBBLE GUM FLAVOR PROFESSIONAL PLAQUE-IDENTIFYING

sodium fluoride paste, dentifrice

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57660-001	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.14 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		

SORBITOL (UNII: 506T60A25R)

HYDRATED SILICA (UNII: Y607T4G8P9)

GLYCERIN (UNII: PDC6A3C0OX)

SODIUM PYROPHOSPHATE (UNII: O352864B8Z)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)

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	BERRY, BUBBLE GUM (Berry Bubble Gum Flavor)	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57660-001- 01	1 in 1 PACKAGE	03/19/2014	
1		116 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:57660-001- 02	1 in 1 PACKAGE	03/19/2014	
2		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	03/19/2014	

Labeler - TJA Health LLC (078799634)

Registrant - TJA Health LLC (078799634)

Establishment			
Name	Address	ID/FEI	Business Operations

TJA Health LLC	078799634	manufacture(57660-001)

Revised: 12/2023 TJA Health LLC