PLUS WHITE XTRA WHITENING- sodium monofluorophosphate paste CCA Industries, Inc.

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.

Plus White Xtra Whitening

Drug Facts

Active ingredient

Sodium Monofluorophosphate 0.884% (0.15% w/v Fluoride ion)

Purpose

Anticavity whitening toothpaste

 $\Box Use$

Aids in the prevention of dental cavities and removal of stains

Warnings

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

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 and older
- Brush teeth thoroughly after each meal, or at least twice a day, or as directed by a dentist or physician
- to minimize swallowing for children under 6, use a pea-sized amount and supervise brushing until good habits are established
- children under 2 years ask a dentist or physician.

Inactive ingredients

Hydrated Silica, Sorbitol, Water (Aqua), Dicalcium Phosphate, Glycerin, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Titanium Dioxide,

Trisodium Phosphate, PVM/MA Copolymer, Sodium Saccharin, Blue 1 (CI 42090).

Questions or comments? Call Toll Free 1-800-595-6230 - www.pluswhite.com

Package Labeling:

Now! XTRA Whiteners Remove Stains Fast





Wine

Tohacco

& Other Tough Stains!

Specially Formulated to Remove:

Coffee

iobacco

& Other Tough Stains!

Fluoride Protection

EVERY DAY WHITENING TOOTHPASTE

With Tartar Control*

DOUBLE ACTION STAIN REMOVERS

Net Wt 3.5 oz/100g

Fluoride Protection

Cool Mint Paste,

MONEY BACK **GUARANTEE**

Complete details available at www.pluswhite.com



Manufactured in the USA for: CCA Industries, Inc., 200 Murray Hill Plwy., E. Rutherford, NJ 07073 USA 27243X-01G PW-B-NA

Cuestions or comments? Call Toll Free1-80 65956 230 • www.pluswhite.com

Trisodum Phosphate, PV MMA Copolymer, Sodium Seccharin, Bue 1 (Cl 42090) Phosphate, Glycerin, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Titanium Dioxide, Inactive ingredients Hydated Slica, Sobitd, Water (Aqua), Dicalcium

swalowingfor children under 6, use a peasized amount and supervise brushing until goodhablis are established • children under 2 yeers esk a dartist or physican. estiminim of a nabile ying to tatheb a yu be to the to the solver seed to 10, learn has a Directions . Adults and children 2 years and dider . Brush tests thoroughly after

or contacta Poison Control Center ight away. If more from used for brushing is accidentally swallowed, get medical help Warmings . Keep out of reach of children under 6 years of age

Use Ads in theprevention of dertial cavities and removal of stairs.

Seatth and a sea of the seat o Purpose Active ingredient

Drug Facts

SEE BOTTOMOF BOX FOR DETAILS. MON EY BACK GUARANTEE

Contains no animal fat.

Drug Facts (continued)



nee D bashaert gaileet Troops you Whole Mouth





anies Action Stain A elduo O anies Apulo Je wA risilo 9

In a ddition, the fluoride works to prate a your teeth a gainst as wite s, while the long-last ng minty ta ste leave s your mouth teet ing retres hed every time you brush. *Plus White toothpaste also helps removeplaque to control tartar.

Plus White's state of the art double action stain remove rs work like no ordinary todhpaste to remove coffee, tea, tobacco, wine and other food and suntace stains. The result? Your teeth will look shades whiter and brighter. Guaranteed,

XTRA Whitening for Whiter, Brighter Teeth, Fast!





#27243X-016



XTRA Whitening for Whiter, Brighter Teeth, Fast!

- Specially Formulated to Remove:
 - Coffee
- Tea
- Wine
- Tobacco
- & Other Food Stains!
- Helps Remove Plaque to Control Tartar
- Fights Cavities

Active ingredient Sodium Monofluorophosphate 0.884% (0.15% w/v Fluoride ion) **Use** Aids in the prevention of dental cavities and removal of stains.

Warnings Keep out of the reach of children under 6 years of age • In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Directions • Adults and children 2 years and older: brush teeth thoroughly after meals or at least twice a day, or as directed by a dentist or physician • To minimize swallowing for children under 6, use a peasized amount and supervise brushing until good habits are established • Children under 2 years: Consult a dentist or physician.



Questions or comments?
Call Toll Free 1-800-595-6230 • www.pluswhite.com

PLUS WHITE XTRA WHITENING

sodium monofluorophosphate paste

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61543-7243	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.5 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)		
GLYCERIN (UNII: PDC6A3C0OX)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

]	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:61543-7243-3	1 in 1 BOX	06/11/2010	
:	l	100 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	06/11/2010	

Labeler - CCA Industries, Inc. (106771041)

Revised: 9/2020 CCA Industries, Inc.