

**PLUS WHITE XTRA- 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 Gel

Drug Facts

Active ingredient

Sodium Monofluorophosphate 0.83% (0.11% fluoride ion)

Purpose

Anticavity whitening toothpaste

Use

aids in the prevention of dental cavities and removal of stains

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 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

Questions or comments?

call Toll Free 1-800-595-6230 • www.pluswhite.com

Package Labeling:

PlusWhite **XTRA** Cool Mint *gel*

#27237

XTRA Whitening for Whiter, Brighter Teeth, Fast!

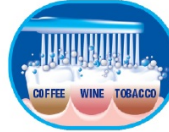
Plus White's state-of-the-art double action stain removers work like no ordinary toothpaste to remove coffee, tea, tobacco, wine and other food and surface stains. The result? Your teeth will look shades whiter and brighter. Guaranteed.

*Plus White toothpaste also helps remove plaque to control tartar. In addition, the fluoride works to protect your teeth against cavities, while the long-lasting minty taste leaves your mouth feeling refreshed every time you brush.

Double Action Stain Removers Polish Away Tough Stains

Helps Remove Plaque to Control Tartar

Leaves Your Whole Mouth Feeling Fresh and Clean



Drug Facts		Drug Facts (continued)	Contains no animal fat.
Active ingredient Sodium monofluorophosphate 0.83% (0.11% fluoride ion).....	Purpose Anticavity whitening toothpaste	<ul style="list-style-type: none"> 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 	
Use aids in the prevention of dental cavities and removal of stains			
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.		Inactive ingredients sorbitol, hydrated silica, glycerin, water (aqua), PEG-32, sodium lauryl sulfate, flavor, PVM/MA copolymer, cellulose gum, trisodium phosphate, sodium phosphate, sodium saccharin, blue 1 (CI 42090), yellow 10 (CI 47005)	
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		Questions or comments? Call Toll Free 1-800-595-6230 • www.pluswhite.com	



FC27237-02 1-800-595-6230
 CORE CARE AMERICA
 65 Challenger Road, Ridgfield Park
 NJ 07660 USA
 Manufactured in the USA



PLUS WHITE XTRA			
sodium monofluorophosphate paste			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61543-7237
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)			FLUORIDE ION	1.1 mg in 1 g
Inactive Ingredients				
Ingredient Name				Strength
SORBITOL (UNII: 506T60A25R)				
HYDRATED SILICA (UNII: Y607T4G8P9)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
SODIUM PHOSPHATE (UNII: SE337SVY37)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-7237-3	1 in 1 BOX	03/15/2019	
1		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: 8/2021

CCA Industries, Inc.