PLUS WHITE WITH PEROXIDE- 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 With Peroxide

Drug Fatcs

Active ingredient

Sodium Monofluorophosphate 0.83% (0.11% w/v fluoride ion)

Purpose

Anticavity whitening toothpaste

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 and older
- b rush 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:

GLYCERIN, HYDRATED SILICA, PROPYLENE GLYCOL, SORBITOL, DICALCIUM PHOSPHATE, SODIUM LAURYL SULFATE, FLAVOR, UREA PEROXIDE, TITANIUM DIOXIDE, SODIUM CARBONATE, CALCIUM PEROXIDE, CARBOMER, SODIUM SACCHARIN, SODIUM BENZOATE.

Questions or comments?

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

Package Labeling:



PLUS WHITE WITH PEROXIDE

sodium monofluorophosphate paste

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61543-7233

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			
GLYCERIN (UNII: PDC6A3C0OX)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SORBITOL (UNII: 506T60A25R)				
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)				
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
CARBAMIDE PERO XIDE (UNII: 31PZ2VAU81)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SO DIUM CARBO NATE (UNII: 45P3261C7T)				
CALCIUM PERO XIDE (UNII: 7FRO2ENO91)				
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:61543-7233-2	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 not final	part356	06/09/2010			

Labeler - CCA Industries, Inc. (106771041)

Revised: 9/2020 CCA Industries, Inc.