

**PLUS WHITE- sodium monofluorophosphate paste, dentifrice
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 Toothpaste with Peroxide

Active Ingredient

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

Purpose

Anticavity Toothpaste

Uses

Aids in the prevention of dental decay.

Warnings

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

Keep out of the reach of children under 6 years of age.

Directions

This toothpaste is formulated for adults 18 and over who smoke tobacco

- It should not be utilized by children under 18 years old without consulting a dentist or physician
- Brush teeth thoroughly, preferably after each meal, or at least twice a day, or when new stains are apparent.

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

Principal Display Panel - Tube 2.0 oz

Plus+White

Plus White TOOTHPASTE with Peroxide

Net Wt 2.0 oz (56.6G) - Fluoride Anticavity Toothpaste

For best results squeeze tube from bottom

NET WT 2.0 OZ (56.6G)



With PEROXIDE Anticavity Toothpaste

XTRA Whitening with Peroxide for Whiter, Brighter Teeth, Fast!

- Gently and Effectively Removes Stains
- Leaves Whole Mouth Feeling Fresh and Clean
- Helps Remove Plaque to Control Tartar
- Fights Cavities

Active ingredient

Sodium Monofluorophosphate 0.83% (0.11% Fluoride ion).....Anticavity 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: 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.

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



Mfd. in the USA, 1099 Wall Street West, Lyndhurst, NJ 07071
240128 TB27233-03 1-800-595-6230

For best results squeeze tube from bottom

NET WT 2.0 OZ (56.6G)



With PEROXIDE Anticavity Toothpaste

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240128 TB27233-03 1-800-595-6230

Principal Display Panel - Carton 2.0 oz

Plus + White

Plus White Toothpaste with Peroxide

NET WT 2.0 oz (56.6G) Fluoride Anticavity Toothpaste

XTRA Whiteners Remove Stains Fast



PlusWhite



With PEROXIDE Anticavity Toothpaste

Tartar Control[†]
Fluoride
Protection



PlusWhite



With PEROXIDE Anticavity Toothpaste

NET WT 2.0 OZ (56.6G)

cca core care AMERICA
1500 West Street
Lakewood, CO 80401
1-800-955-5830
PC22-03



Directions Brush with toothpaste after each meal or at least twice a day or as directed by a dentist or physician. Rinse with water and allow to dry.	Warnings Keep out of reach of children under 6 years of age. If you have had a recent dental procedure, consult your dentist before using. Avoid use if you have a recent dental procedure. Avoid use if you have a recent dental procedure.
Active Ingredient Sodium Peroxide 1.2%, 12.5% (w/w)	Purpose Anticavity toothpaste
Drug Facts (continued) Contains no alcohol.	

Xtra Whitening for Whiter, Brighter Teeth, Fast!

PlusWhite XTRA Whitening with Peroxide and Fluoride is a new and exciting way to whiten your teeth. It's the only toothpaste that whitens your teeth in just 2 minutes. Plus, it's also a fluoride toothpaste that helps protect your teeth from cavities.

- Keeps Teeth Whiter, Brighter, Longer
- Removes Stains Fast
- Keeps Teeth Stronger and Healthier

877220

XTRA Whiteners Remove Stains Fast



PlusWhite



With PEROXIDE Anticavity Toothpaste

Tartar Control[®]
Fluoride
Protection

PlusWhite



With PEROXIDE Anticavity Toothpaste

Cool Mint
Flavor

NET WT 2.0 OZ (56.6G)

cca core care AMERICA
1000 West Street West
Lyndhurst, NJ 07037
1-800-995-8220 • www.pluswhite.com



Drug Facts
Warnings
Directions
Other information
Contains no alcohol.

Xtra Whitening for Whiter, Brighter Teeth, Fast!

PlusWhite XTRA Whitening is a toothpaste that whitens teeth fast. It contains a powerful whitening agent that works to remove stains and brighten your smile. PlusWhite XTRA Whitening is a toothpaste that whitens teeth fast. It contains a powerful whitening agent that works to remove stains and brighten your smile.

Keep Your Teeth Whiter, Brighter, Longer!

PlusWhite XTRA Whitening is a toothpaste that whitens teeth fast. It contains a powerful whitening agent that works to remove stains and brighten your smile.

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PLUS WHITE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61543-1751
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.83 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
CALCIUM PEROXIDE (UNII: 7FRO2ENO91)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-1751-3	1 in 1 CARTON	05/22/2018	
1		56.6 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	05/22/2018	

Labeler - CCA Industries, Inc. (106771041)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(61543-1751)