

**PLUS WHITE SMOKERS WHITENING- 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 Smokers Whitening

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 Sorbitol, Hydrated Silica, Water (Purified), Dicalcium Phosphate, Glycerin, PVM/MA Copolymer, Flavor, Sodium lauryl Sulfate, Cellulose Gum, Titanium Dioxide, Trisodium Phosphate, Sodium Saccharin, Blue 1, Yellow 5

Questions or comments? Call Toll Free 1-800-595-6230

- www.pluswhite.com

Principal Display Panel - Tube 3.5 oz

Plus+White

THE SMOKER'S WHITENING TOOTHPASTE

Net Wt 3.5 oz (100G) - Fluoride Anticavity Toothpaste

For best results squeeze tube from bottom

PlusWhite[®] **SMOKERS'** Whitening

TOBACCO STAINS REMOVED FAST **Toothpaste**

Cooling Peppermint Flavor Eliminates Tobacco Breath
Fluoride Anti Cavity Protection • Net Wt 3.5 oz/100g

Active Ingredient

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

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Mfd. in the USA, 65 Challenger Road Ridgefield Park, NJ 07660 USA
TB27236-03 1-800-595-6230 240158

Purpose

Anticavity toothpaste

For best results squeeze tube from bottom

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TB27236-03 1-800-595-6230 240158

Principal Display Panel - Carton 3.5 oz



+ White
 The Smokers Whitening Toothpaste
 NET WT 3.5 oz (100G) Fluoride Anticavity Toothpaste

Plus

The Smokers' Whitening Toothpaste

TOBACCO STAINS REMOVED FAST



PlusWhite **SMOKERS' Whitening**
TOBACCO STAINS REMOVED FAST Fluoride Anticavity Toothpaste

TOBACCO STAINS REMOVED FAST



FLUORIDE PROTECTION

PlusWhite **SMOKERS' Whitening**
TOBACCO STAINS REMOVED FAST Fluoride Anticavity Toothpaste

Cool Peppermint Flavor

NET WT 3.5 OZ (100g)

TOBACCO STAINS REMOVED FAST

Fluoride Anticavity Toothpaste

core care AMERICA
Manufactured in the USA
85 Challenge Road, Royalwood Park
NJ 07068 USA
973-980-3900 • www.PlusWhite.com



0 18515 27256 2

PlusWhite

REMOVES TOBACCO STAINS FAST
Special toothpaste made just for smokers to remove brown tobacco stains and white discoloration all at the same time.
Plus White Smokers' Whitening Toothpaste contains a special combination of stain removers precisely formulated to remove stains and discoloration caused by smoking. To provide white teeth and brighten Smokers' Whitening Toothpaste also removes plaque to control tartar and provides fluoride protection against decay. And its cooling peppermint flavor eliminates tobacco taste for hours. Removes coffee stains too.
This is the toothpaste smokers have been waiting for!
Removing Stains, Whitening Teeth is Plus White's Business.

PlusWhite **SMOKERS' Whitening**

Drug Facts
Active Ingredient
Fluoride (Sodium Fluoride) 0.25%, 11% FPP, 15% FPP
Purpose
Toothpaste
Warnings
Keep out of reach of children under 6 years of age. If more than used for brushing or occasional rinsing, get medical help or contact a Poison Control Center right away.
Directions
Brush teeth as directed. To achieve best results, brush for at least two minutes, at least twice a day. Rinse with water. Do not swallow.
Active Ingredients
Sodium Fluoride 0.25%, 11% FPP, 15% FPP
Questions or comments?
Call toll free 1-800-995-4338 • www.PlusWhite.com

The Smokers' Whitening Toothpaste

TOBACCO STAINS REMOVED FAST



PlusWhite **SMOKERS' Whitening**
TOBACCO STAINS REMOVED FAST Fluoride Anticavity Toothpaste

TOBACCO STAINS REMOVED FAST



FLUORIDE PROTECTION

PlusWhite **SMOKERS' Whitening**
TOBACCO STAINS REMOVED FAST Fluoride Anticavity Toothpaste



NET WT 3.5 OZ (100g)

TOBACCO STAINS REMOVED FAST

Fluoride Anticavity Toothpaste

core care AMERICA Manufactured in the USA
85 Challenge Road, Roycefield Park
NJ 07060 USA
800-995-9959 • 94-9262723



502114

Questions or comments?
Call the toll free 1-800-995-9959 • www.PlusWhite.com

Warnings
Keep out of reach of children under 6 years of age. If more than used for brushing or whitening, discontinue use or consult a health care professional.

Directions
Brush teeth as directed. For whitening, brush for 2 minutes. For stain removal, brush for 2 minutes. For fluoride protection, brush for 2 minutes. For cavity protection, brush for 2 minutes.

Drug Facts
Active ingredient: Fluoride (Sodium Fluoride) 0.25% (11% Fluoride ion)

Purpose
Whitening, cavity protection, fluoride protection

REMOVES TOBACCO STAINS FAST

PlusWhite **SMOKERS' Whitening**

Brush! A special toothpaste made just for smokers to remove brown tobacco stains and whiten discolored teeth all the time!

Plus White Smokers' Whitening Toothpaste contains a special combination of stain removers specially formulated to remove stains and discoloration caused by smoking. To provide whitening, Plus White Smokers' Whitening Toothpaste also contains a special stain remover and provides fluoride protection against cavities. And its cooling peppermint flavor eliminates tobacco taste for hours. Removes coffee stains too!

This is the toothpaste smokers have been waiting for! Removing stains, whitening teeth is Plus White's business.

PlusWhite

PlusWhite
LOT
EXP

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The Smokers' Whitening Toothpaste

TOBACCO STAINS REMOVED FAST



PlusWhite **SMOKERS' Whitening**
TOBACCO STAINS REMOVED FAST Fluoride Anticavity Toothpaste

TOBACCO STAINS REMOVED FAST



FLUORIDE PROTECTION

PlusWhite **SMOKERS' Whitening**
TOBACCO STAINS REMOVED FAST Fluoride Anticavity Toothpaste



NET WT 3.5 OZ (100g)

TOBACCO STAINS REMOVED FAST

Fluoride Anticavity Toothpaste

core care AMERICA Manufactured in the USA
80 Challenge Road, Roycefield Park
NJ 07060 USA
800-995-9959 • 908-272-2722 • www.PlusWhite.com



502114

Questions or comments?
Call the toll free 1-800-995-9959 • www.PlusWhite.com

Directions
Apply toothpaste to a wet toothbrush. Brush for 2 minutes, 2-3 times a day. Spit out the toothpaste and rinse your mouth with water. Do not swallow. For best results, use after meals. For more information, visit our website at www.PlusWhite.com.

Warnings
Keep out of reach of children under 6 years of age. If more than one child uses this product, get medical help or contact a Poison Control Center right away.

Drug Facts
Active ingredient: Fluoride Anticavity Toothpaste. Contains 0.24% Fluoride Ion.

Purpose
Whitening toothpaste.

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REMOVES TOBACCO STAINS FAST

Plus White Smokers' Whitening Toothpaste contains a special formula that helps to remove tobacco stains and whitens discolored teeth all the time. This special toothpaste made just for smokers to remove stains and discoloration caused by smoking. To provide white, bright teeth, Smokers' Whitening toothpaste also contains a special active ingredient that provides fluoride protection against decay and its coating properties. Plus, Smokers' Whitening Toothpaste contains a special formula that helps to remove tobacco stains and whitens discolored teeth all the time.

Removing Stains, Whitening Teeth is Plus White's Business.

This is the toothpaste smokers have been waiting for! Plus White Smokers' Whitening Toothpaste is a special formula that helps to remove tobacco stains and whitens discolored teeth all the time. This special toothpaste made just for smokers to remove stains and discoloration caused by smoking. To provide white, bright teeth, Smokers' Whitening toothpaste also contains a special active ingredient that provides fluoride protection against decay and its coating properties. Plus, Smokers' Whitening Toothpaste contains a special formula that helps to remove tobacco stains and whitens discolored teeth all the time.

PlusWhite



PLUS WHITE SMOKERS WHITENING

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1543-1554
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)	
WATER (UNII: 059QF0K00R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	

TRISODIUM DIPHOSPHATE (UNII: AR7OGW33N1)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-1554-3	1 in 1 CARTON	01/31/2018	
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	01/31/2018	

Labeler - CCA Industries, Inc. (106771041)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(61543-1554)