

**PLUS WHITE COFFEE- 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.*

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**Plus White Coffee Toothpaste**

**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,

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

**- [www.pluswhite.com](http://www.pluswhite.com)**

**Principal Display Panel - Tube 3.5 oz**

Plus+White

Plus White Coffee TOOTHPASTE

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

# PlusWhite<sup>®</sup> **COFFEE Drinkers'**

**REMOVES COFFEE STAINS FAST Anticavity Toothpaste**

**NET WT 3.5 OZ (100g) • Fluoride Protection • Helps Remove Plaque to Control Tartar**

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Sodium monofluorophosphate 0.83% (0.11% fluoride ion)

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**Directions:** This toothpaste is formulated for adults 18 and over who drink coffee.

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**Questions or comments?**

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AMERICA

Mfd. in the USA, 1099 Wall Street West, Lyndhurst, NJ 07071  
TB27224-03

1-800-595-6230

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TB27224-03 1-800-595-6230

Principal Display Panel - Carton 3.5 oz





Plus + White

Plus White Coffee Toothpaste

NET WT 3.5 oz (100G) Fluoride Anticavity Toothpaste







**Coffee Drinkers' Whitening Toothpaste** Removes Tough Built up Stains



**PlusWhite**

**COFFEE Drinkers'**

REMOVES COFFEE STAINS FAST Anticavity Toothpaste

FLUORIDE CAVITY PROTECTION

**PlusWhite**

**COFFEE Drinkers'**

NET WT 3.5 OZ (100G) REMOVES COFFEE STAINS FAST Anticavity Toothpaste



Cool Mint Flavor

**Satisfaction Guaranteed**

If you are not completely satisfied with your purchase, please return it for a full refund. No questions asked. No expiration date. No cash back. No receipt necessary. No return shipping charges. No restocking fees. No handling charges. No taxes. No duties. No customs charges. No import charges. No export charges. No international shipping charges. No insurance charges. No brokerage charges. No duties and taxes. No import and export restrictions. No restrictions on use. No restrictions on quantity. No restrictions on destination. No restrictions on origin. No restrictions on carrier. No restrictions on mode of transport. No restrictions on route. No restrictions on transit time. No restrictions on delivery date. No restrictions on delivery location. No restrictions on delivery time. No restrictions on delivery conditions. No restrictions on delivery terms. No restrictions on delivery conditions. No restrictions on delivery terms. No restrictions on delivery conditions. No restrictions on delivery terms.

[www.PlusWhite.com](http://www.PlusWhite.com)

core care AMERICA  
 17073 NW 36th Street  
 Miami, FL 33187  
 305-555-0901  
 03-242724



**Questions or comments?**  
 Call toll free 1-800-585-8228 • [www.PlusWhite.com](http://www.PlusWhite.com)

**Directions:**  
 • This toothpaste is formulated for adults 13 and over who drink coffee.  
 • Brush teeth thoroughly, preferably after each meal, or at least twice a day, or when you wake up.  
 • Rinse with water. Do not swallow. Spit out excess toothpaste.  
 • Avoid eating or drinking for 30 minutes after brushing. Avoid eating or drinking acidic foods and beverages for 30 minutes after brushing.

**Warnings:**  
 • Do not use if you are allergic to any of the ingredients.  
 • Do not use if you are pregnant or nursing.  
 • Do not use if you are taking any medication.

**Drug Facts:**  
 Active ingredient: Fluoride (0.24% w/w), Triclosan (0.06% w/w)  
 Purpose: Anticavity, whitening

©2014  
 Contains no animal by-products

**Recommended For Coffee Drinkers**  
 The toothpaste formulated with Special Stain Removers  
 Anticavity Whitening  
 PlusWhite  
 COFFEE Drinkers'

**Recommended For Coffee Drinkers**  
 You love coffee, but it can stain your teeth, leaving them brownish and dull. That's why Plus White Coffee Drinkers' Whitening Toothpaste contains a special combination of stain-removers specially formulated to remove the stains and yellowing caused by coffee, to provide whiter and brighter teeth. Coffee Drinkers' Whitening Toothpaste also helps remove plaque to control tartar and provides fluoride protection against cavities. And its cool, minty flavor makes brushing "coffee drinker" fun!  
 Now you can enjoy your coffee and let Plus White remove the stains.  
**Removing Stains, Whitening Teeth is Plus White's Business.**





**Coffee Drinkers' Whitening Toothpaste** Removes Tough Built up Stains



**PlusWhite**

**COFFEE Drinkers'**

REMOVES COFFEE STAINS FAST Anticavity Toothpaste

FLUORIDE CAVITY PROTECTION

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NET WT 3.5 OZ (100G) REMOVES COFFEE STAINS FAST Anticavity Toothpaste



Cool Mint Flavor

**Satisfaction Guaranteed**

If you are not completely satisfied with your purchase, please return it to us for a full refund. No questions asked. We'll make it right. Call 1-800-858-8228 for more information. [www.PlusWhite.com](http://www.PlusWhite.com)

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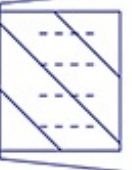
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**Directions:** This toothpaste is formulated for adults 13 and over who drink coffee. Brush twice daily, morning and night, for 2 minutes. Spit out the toothpaste and rinse your mouth with water. Do not swallow. For best results, use with a soft toothbrush. **Warnings:** Keep out of reach of children under 12 years of age. If you are pregnant or nursing, consult your medical doctor or dentist before use. **Drug Facts:** Use only as directed. **Active Ingredients:** Fluoride (0.25% by weight), Hydroxyapatite (0.05% by weight). **Purpose:** Anticavity toothpaste.

**Recommended For Coffee Drinkers**  
 You love coffee, but it can stain your teeth, leaving them brownish and dull. That's why Plus White Coffee Drinkers' Whitening Toothpaste contains a special combination of stain-removers specially formulated to remove the stains and yellowing caused by coffee, to provide whiter and brighter teeth. Coffee Drinkers' Whitening Toothpaste also helps remove plaque to control tartar and provides fluoride protection against cavities. And its cool, minty flavor makes brushing "coffee drinker" fun. Now you can enjoy your coffee and let Plus White remove the stains. **Plus White's Business.** Removing Stains, Whitening Teeth is

PlusWhite  
 LOT  
 EXP

PlusWhite



©2014

**Coffee Drinkers' Whitening Toothpaste** Removes Tough Built up Stains



**PlusWhite**

**COFFEE Drinkers'**

REMOVES COFFEE STAINS FAST **Anticavity Toothpaste**

FLUORIDE CAVITY PROTECTION

**PlusWhite**

**COFFEE Drinkers'**

NET WT 3.5 OZ (100G) **REMOVES COFFEE STAINS FAST** **Anticavity Toothpaste**



Cool Mint Flavor

**Satisfaction Guaranteed**

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**core care**  
A M E R I C A  
Manufactured in the USA  
17073 NW 34th Street  
Miami, FL 33187  
305-565-0901



**Questions or comments?**  
Call 1-800-858-8228 • [www.PlusWhite.com](http://www.PlusWhite.com)

**Directions**  
Apply a pea-sized amount of toothpaste to your toothbrush. Brush your teeth for two minutes, twice a day. Rinse thoroughly. Do not swallow. For best results, use after meals or after coffee. For more information, visit [www.PlusWhite.com](http://www.PlusWhite.com).

**Warnings**  
Keep out of reach of children. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. If irritation occurs, discontinue use. For more information, visit [www.PlusWhite.com](http://www.PlusWhite.com).

**Use only in the presence of dental decay.**

**Drug Facts**  
**Active ingredient:** Fluoride (0.25% by weight as NaF) (Anticavity)

**Purpose**  
Removes coffee stains. Whitens teeth. Provides fluoride for cavity protection.

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**Recommended For Coffee Drinkers**  
The toothpaste formulated with Special Stain Removers

**PlusWhite**  
**COFFEE Drinkers'**

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## PLUS WHITE COFFEE

sodium monofluorophosphate paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61543-1702
<b>Route of Administration</b>	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: Y607T4G8P9)	



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)	
SORBITOL (UNII: 506T60A25R)	

### Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61543-1702-3	1 in 1 CARTON	06/30/2018	
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	06/30/2018	

**Labeler** - CCA Industries, Inc. (106771041)

**Registrant** - Sheffield Pharmaceuticals LLC (151177797)

### Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(61543-1702)