

**PLUS WHITE EXTRA WHITENING- sodium monofluorophosphate paste, dentifrice**  
**CCA Industries LLC**

*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 Extra Whitening Toothpaste**

**Active ingredient**

Sodium Monofluorophosphate 0.83% (0.15% w/v fluoride ion)

**Purpose**

Anticavity whitening toothpaste

**Use**

Aids in the removal of stains and 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 reach of children under 6 years of age.**

**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 the age of 6, use a pea size amount and supervise brushing until good habits are established
- children under 2 years of age ask a dentist or physician

Inactive ingredients Hydrated Silica, Sorbitol, Water (Aqua), Dicalcium Phosphate, Glycerin, PVM/MA Copolymer, Sodium Lauryl Sulfate, Flavor, 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)

**Plus White Extra Whitening -Carton 3.5 oz**

Plus+White Extra Whitening

Fluoride Protection

Fluoride Anticavity toothpaste

NET WT. 3.5 oz (100G)



**Plus White Extra Whitening -Tube 3.5 oz**

Plus +White Extra Whitening

Fluoride Protection

NET WT 3.5 oz (100G)

<b>Drug Facts</b> (continued)		Contains no animal fat.
<ul style="list-style-type: none"> <li>• No medicines are present for children under 6, use a pea sized amount and supervise brushing and flossing. Adults are supervised.</li> <li>• children under 2 years old consult a dentist or physician.</li> </ul>		
<b>Active Ingredient</b> Sodium monofluorophosphate 0.24% (0.11% w/w fluoride ion)	<b>Purpose</b> Anticavity toothpaste	
<b>Other Active</b> Listed in the prevention of dental caries.		
<b>Warnings</b> Keep out of reach of children under 6 years of age. If more than used for 1 year in accordance with directions, get medical help or contact a Poison Control Center, eight areas.		
<b>Directions</b> • 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		
<b>Conditions of Sale</b> Call toll free 1-800-368-6230 • www.pluswhite.com		

NET WT 3.5 OZ (100G)

FLUORIDE  
PROTECTION



**XTRA Whitening for Whiter, Brighter Teeth, Fast!**

▶ **Specially Formulated to Remove:**

- Coffee
  - Tea
  - Wine
  - Tobacco
- & Other Food Stains!

▶ **Helps Remove Plaque to Control Tartar**

▶ **Fights Cavities**

**Active ingredient**

Sodium Monofluorophosphate 0.83% (0.11% fluoride ion).....**Purpose**  
Use Aids in the prevention of dental cavities. Anticavity toothpaste

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



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TB27243-04 1-800-595-6230 240149

**PLUS WHITE EXTRA WHITENING**

sodium monofluorophosphate paste, dentifrice

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61543-1502
Route of Administration	DENTAL		

**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)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
TRIBASIC SODIUM PHOSPHATE (UNII: A752Q30A6X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

### 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:61543-1502-3	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 LLC (106771041)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(61543-1502)