## ASSURED ORAL HEALTH FRESH MINT- cetylpyridinium chloride rinse Greenbrier International, 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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#### **Assured Fresh Mint Oral Health Rinse**

For better oral hygiene and fresher breath

Drug Facts

#### Active ingredient

Cetylpyridinium chloride 0.07%

#### **Purpose**

Antigingivitis, Antiplaque

Usehelps control plaque that leads to gingivitis

#### Warnings

#### Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. These may be symptoms of periodontitis, a serious form of gum disease.

**Keep out of reach of children under 6 years of age.** If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- adults and children 6 years & older: rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day
- do not swallow
- children 6 to under 12 years of age: supervise use
- when used after brushing. rinse mouth with water first
- children under 6 years of age: do not use

#### Other information

• this rinse is not intended to replace brushing or flossing

*Inactive ingredients* water, glycerin, flavor, poloxamer 188, sodium saccharin, propylene glycol, sodium benzoate, sucralose, benzoic acid, blue 1

This rinse may cause temporary staining to the surface of the teeth. This is not harmful, and adequate brushing may prevent its occurrence.

\*This product is not manufactured or distributed by Proctor & Gamble, distributor of Crest Pro-Health Multi-Protection Alcohol Free Rinse - Refreshing Clean Mint.

#### DISTRIBUTED BY: GREENBRIER INTERNATIONAL INC.

#### **500 VOLVO PARKWAY, CHESAPEAKE, VA 23320**

COMPARES TO ACTIVE INGREDIENTS OF CREST PRO-HEALTH®\*

Assured™

FRESH MINT

#### **ORAL HEALTH RINSE**

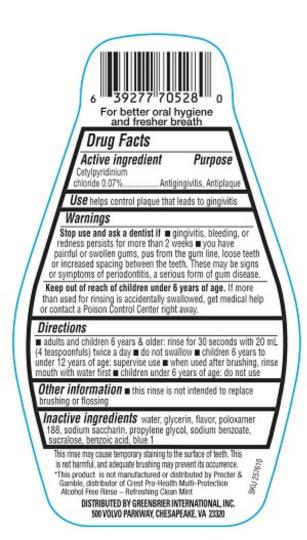
#### **MULTI-ACTION ALCOHOL-FREE ANTISEPTIC**

ANTIGINGIVITIS / ANTIPLAQUE

Kills Germs that Cause Bad Breath, Plaque and the Gum Disease Gingivitis Alcohol Free, Freshens Breath

16.9 FL OZ (500 mL)





#### ASSURED ORAL HEALTH FRESH MINT

cetylpyridinium chloride rinse

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0320
Route of Administration	ORAL		

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength CETYLPYRIDINIUM CHLORIDE (UNII: D90M4SK49P) (CETYLPYRIDINIUM - CETYLPYRIDINIUM CHLORIDE UNII:CUB7JI0JV3) CETYLPYRIDINIUM CHLORIDE 0.07 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
WATER (UNII: 059QF0KO0R)			
BENZOIC ACID (UNII: 85KN0B0MIM)			

POLOXAMER 188 (UNII: LQA7B6G8JG)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics		
Color	blue	Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

ı	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:33992- 0320-7	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/21/2019		

Marketing In	Marketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/21/2019	

### **Labeler -** Greenbrier International, Inc. (610322518)

Revised: 8/2021 Greenbrier International, Inc.