

**AURORA ALCOHOL FREE CLEAN MINT- cetylpyridinium chloride mouthwash**  
**Apollo Health and Beauty Care**

*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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**DRUG FACTS**

**Active ingredient**

Cetylpyridinium Chloride 0.07%

**Purpose**

Antiplaque/Antigingivitis

**Uses**

- Helps reduce and prevent plaque and gingivitis.
- Helps control bacteria plaque that contributes to the development of gingivitis and bleeding gums.

**Warnings**

Ask a dentist if symptoms persist or condition worsens after regular use.

**Keep out of reach of children.**

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately (1-800-222-1222).

**Directions**

- Use after your normal brushing and flossing routine; rinse toothpaste from mouth prior to use.
- **Adults and children 6 years of age and older:** Rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day.
- do not swallow.
- children 6 years to under 12 years of age: supervise use.
- **children under 6 years of age: do not use.**

**Other information**

Store at room temperature.

**Inactive ingredients**

Water (Aqua), Glycerin, Poloxamer 407, Flavor, Sodium Saccharin, Methylparaben, Sucralose, Propylparaben, Blue 1 (CI 42090).

**Questions or comments?**

1-866-695-3030

**Label Copy**



AURORA ALCOHOL FREE CLEAN MINT			
cetylpyridinium chloride mouthwash			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63148-553
<b>Route of Administration</b>	BUCCAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7J10JV3)	CETYL PYRIDINIUM CHLORIDE	0.7 mg in 1 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	WATER (UNII: 059QF0KO0R)		
	GLYCERIN (UNII: PDC6A3C0OX)		

<b>POLO XAMER 407</b> (UNII: TUF2IVW3M2)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>METHYLPARABEN</b> (UNII: A2I8C7H9T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-553-50	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/14/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/14/2016	

**Labeler** - Apollo Health and Beauty Care (201901209)

**Registrant** - Apollo Health and Beauty Care (201901209)

### Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(63148-553)

Revised: 6/2016

Apollo Health and Beauty Care