

## **ANTIPLAQUE SOLUTION- cetylpyridinium chloride mouthwash**

### **Sage Products 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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### **Antiplaque Solution**

#### ***Active ingredient***

ANTIPLAQUE:  
Cetylpyridinium chloride .05%

#### ***Purpose***

Antigingivitis/antiplaque

#### ***Uses***

Aids in the removal and prevention of 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 increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

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

#### ***Directions***

- **Before opening**, turn package over, burst solution packet with thumbs.
- Peel lid to open.
- Remove Mouth Moisturizer and Applicator Swab.
- Attach Toothbrush to suction line.
- Clean teeth and oral cavity for approximately one minute.
- To suction, place thumb over port.
- To clear tubing, rinse with sterile saline or appropriate solution.
- Discard Toothbrush. Reattach Covered Yankauer to suction line.
- Place Mouth Moisturizer on Applicator Swab.
- Apply as needed to lips and inside mouth.

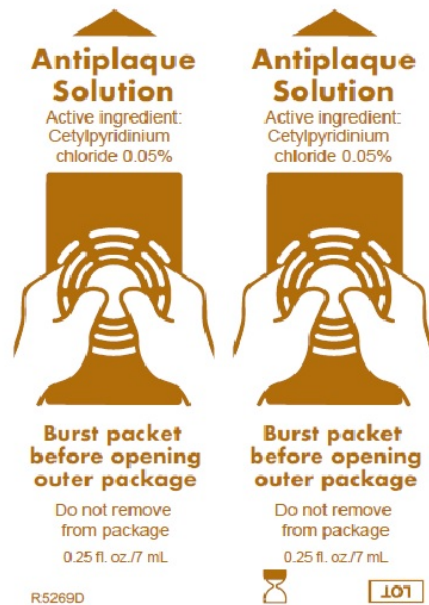
- Adults and children 12 years of age and older: use two times daily or as directed by a dentist. Do not swallow the solution.
- Children ages 6 to 12 years: supervise use.
- Children under 6 years of age: do not use.
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

### ***Inactive ingredients***

Water, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, FD&C Blue #1

### ***Questions***

Call toll-free 800-323-2220



# ANTIPLAQUE SOLUTION

cetylpyridinium chloride mouthwash

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53462-275 |
| <b>Route of Administration</b> | BUCCAL         |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength        | Strength          |
|--|--------------------------|-------------------|
| <b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYLPIRIDINIUM - UNII:CUB7J10JV3) | CETYLPIRIDINIUM CHLORIDE | 0.5 mg<br>in 1 mL |

## Inactive Ingredients

| Ingredient Name                                   | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                   |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)                |          |
| <b>PEPPERMINT</b> (UNII: V95R5KMY2B)              |          |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)       |          |
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)          |          |
| <b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)          |          |
| <b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP) |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)     |          |

## Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53462-275-60 | 7 mL in 1 PACKET; Type 0: Not a Combination Product | 01/09/2009           |                    |

## Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part356                                  | 01/09/2009           |                    |

**Labeler** - Sage Products LLC (054326178)