

ANTIPLAQUE SOLUTION- cetylpyridinium chloride mouthwash
Sage Products LLC

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.

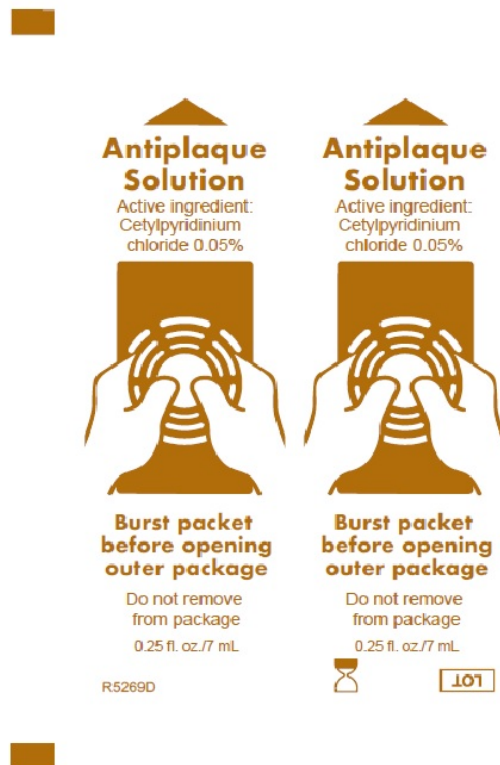
- Use a bite block when performing oral care on patients with altered levels of consciousness or those who cannot comprehend commands.
- Ensure foam is intact after use. If not, remove any particles from oral cavity.

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



cetylpyridinium chloride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-275
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PEPPERMINT (UNII: V95R5KMY2B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (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 Drug	M022	01/09/2009	

Labeler - Sage Products LLC (054326178)

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Sage Products LLC