

**ANTISEPTIC ORAL RINSE- 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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**Antiseptic Oral Rinse**

***Active ingredient***

Cetylpyridinium chloride .05%

***Purpose***

Antiseptic Rinse

***Use***

Helps reduce chance of infection in minor oral irritation.

***Warnings***

**Stop use and ask a doctor if:**

- Sore mouth symptoms do not improve in 7 days.
- Swelling, rash or fever develops.
- Irritation, pain or redness persists or worsens.

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

***Directions***

- Use up to 4 times daily or as directed by a dentist or doctor.
- Adults and children 3 years and over: rinse mouth for approx. one minute with 1/2 Tbsp., or use topically (dip into bottle) with clean Toothette<sup>®</sup> Oral Swab. Instruct to expectorate.
- Children under 12 years of age: supervise use.
- Children under 3 years of age: consult a dentist or doctor.

**Inactive Ingredients**

Water, sorbitol, peppermint flavor, potassium sorbate, polysorbate 80, polysorbate 20, citric acid, Blue 1 (CI42090)

***Questions?***

Call toll free 800-323-2220

## Antiseptic Oral Rinse



### ANTISEPTIC ORAL RINSE

cetylpyridinium chloride mouthwash

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53462-175
Route of Administration	BUCCAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	0.5 mg in 1 mL
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### 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:53462-175-60	7 mL in 1 PACKET; Type 0: Not a Combination Product	12/28/2001	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/21/2000	

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

Revised: 2/2022

Sage Products LLC