

**CEPACOL ANTIBACTERIAL- cetylpyridinium chloride liquid**  
**RB Health (US) 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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**Cēpacol®**  
**ANTIBACTERIAL**  
**MULTI-PROTECTION MOUTHWASH**

***Drug Facts***

**Active ingredient**

Cetylpyridinium chloride 0.05%

**Purpose**

Antigingivitis/Antiplaque

**Uses**

helps prevent and reduce plaque that leads to:

- gingivitis, an early form of gum disease
- bleeding gums

**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 the 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 12 years of age and older: vigorously swish 20 milliliters of rinse between your teeth twice a day for 30 seconds and then spit out. Do not swallow the rinse
- children 6 years to under 12 years of age: supervise use
- children under 6 years of age: do not use.

## Other Information

- this rinse is not intended to replace brushing or flossing
- store at room temperature 20-25°C (68-77°F)
- protect from humidity

## Inactive ingredients

purified water, alcohol 14% v/v, glycerin, sodium phosphate dibasic, eucalyptus oil, polysorbate 80, methyl salicylate, cinnamon oil, peppermint oil, saccharin sodium, sodium phosphate monobasic anhydrous, menthol, edetate disodium, FD&C Yellow #5

## Questions?

**1-888-963-3382** You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser  
Parsippany, NJ 07054-0224

## PRINCIPAL DISPLAY PANEL - 710 mL Bottle Label

NDC 63824-790-80

**Cēpacol®**

### **ANTIBACTERIAL\*** **MULTI-PROTECTION MOUTHWASH**

CPC-Antigingivitis/Antiplaque Oral Rinse

\*Kills Germs That Cause Bad Breath

- **Reduces Plaque**
- **Freshens Breath**

### **#1 BRAND IN HOSPITALS**

**TO OPEN:** Squeeze both raised finger pads on cap and continue to squeeze while turning.

**TO CLOSE:** Turn cap until it locks completely.

**24 FL. OZ. (710 mL)**

0336220  
062111

NDC 63824-790-80

# Cēpacol<sup>®</sup>

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Contains FD&C Yellow #5  
**TAMPER EVIDENT: Do not use if printed seal over cap is torn or missing.**

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 Parsippany, NJ 07054-0224  
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## CEPACOL ANTIBACTERIAL

cetylpyridinium chloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-790
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Cetylpyridinium chloride</b> (UNII: D9OM4SK49P) (Cetylpyridinium - UNII:CUB7J10JV3)	Cetylpyridinium chloride	0.05 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>CINNAMON OIL</b> (UNII: E5GY4I6YCZ)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	

**SACCHARIN SODIUM** (UNII: SB8ZUX40TY)

**SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS** (UNII: KH7I04HPUU)

**MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A)

**EDETATE DISODIUM** (UNII: 7FLD91C86K)

**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-790-80	1 in 1 CARTON	06/22/2011	
1		710 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	06/22/2011	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 6/2022

RB Health (US) LLC