

**ORAJLE ANTI-BACTERIAL RINSE FOR BLEEDING GUMS - cetylpyridinium chloride liquid
Church & Dwight Co., Inc.**

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.

DRUG FACTS

Active ingredient	Purpose
Cetylpyridinium chloride 0.1%	Antigingivitis/Antiplaque

Uses

helps prevent plaque that leads to
gingivitis
bleeding gums

Warnings

When using this product do not swallow

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 years of age. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

Directions remove imprinted safety seal from bottle cap; to remove child-resistant cap, squeeze smooth sides of cap while turning. Reclose tightly.

Adults and children 6 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

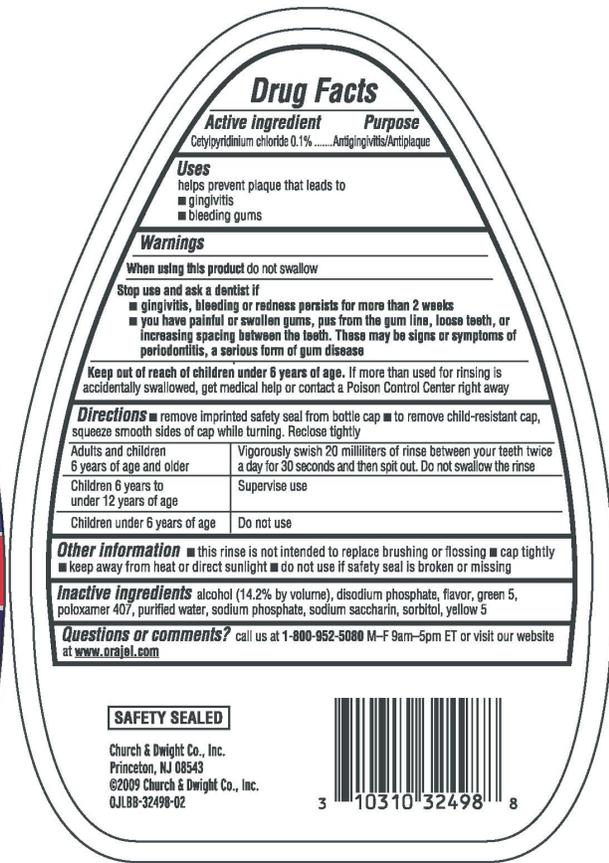
Other information this rinse is not intended to replace brushing or flossing ; cap tightly; keep away from heat or direct sunlight; do not use if safety seal is broken or missing.

Inactive ingredients alcohol (14.2% by volume), disodium phosphate, flavor, green 5, poloxamer 407, purified water, sodium phosphate, sodium saccharin, sorbitol, yellow 5

Questions or comments? call us at **1-800-952-5080** M-F 9am-5pm ET or visit our website at www.oraljel.com

Orajel Anti-Bacterial Rinse
for Bleeding Gums 16 oz.

Label image



ORAJEL ANTI-BACTERIAL RINSE FOR BLEEDING GUMS

cetylpyridinium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-721
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7J10JV3)	CETYLPYRIDINIUM CHLORIDE	.001 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PHOSPHATE ION (UNII: NK08V8K8HR)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-721-16	473.2 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/30/2010	

Labeler - Church & Dwight Co., Inc. (001211952)**Establishment**

Name	Address	ID/FEI	Business Operations
Accupac, Inc.		071609663	manufacture

Revised: 7/2010

Church & Dwight Co., Inc.