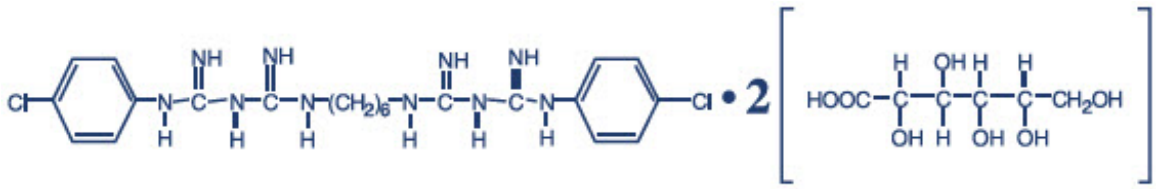
PERIOGARD ALCOHOL FREE- chlorhexidine gluconate rinse
Colgate Oral Pharmaceuticals, Inc.

Colgate®
PerioGard®
(Chlorhexidine Gluconate
Oral Rinse USP, 0.12%)

NDC 0126-0282-16

DESCRIPTION

PerioGard® (Chlorhexidine Gluconate Oral rinse USP, 0.12%) is an oral rinse containing 0.12% chlorhexidine gluconate (1,1'-hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, propylene glycol, glycerin, sorbitol, polyoxyl 40 hydrogenated castor oil, flavor, cetylpyridinium chloride, and FD&C blue no. 1. PerioGard® product is a near neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:



CLINICAL PHARMACOLOGY

PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) provides antimicrobial activity during oral rinsing. The clinical significance of chlorhexidine gluconate oral rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months' use.

Use of chlorhexidine gluconate oral rinse USP, 0.12% in a six-month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorhexidine gluconate oral rinse USP, 0.12% use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

PHARMACOKINETICS

Pharmacokinetic studies with a chlorhexidine gluconate oral rinse USP, 0.12% indicate approximately 30% of the active ingredient is retained in the oral cavity following rinsing. This retained drug is slowly released into the oral fluids.

Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 µg/g in humans 30 minutes after they

ingested a 300-mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATIONS AND USAGE

PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. PerioGard® has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS

PerioGard® should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS

The effect of PerioGard® on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing with users of chlorhexidine gluconate oral rinse USP, 0.12% compared with control users. It is not known if chlorhexidine gluconate use results in an increase of subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine. SEE CONTRAINDICATIONS.

PRECAUTIONS

General

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) should not be used as a major indicator of underlying periodontitis.

2. PerioGard® can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in tooth staining. In clinical testing, 56% of the chlorhexidine gluconate oral rinse USP, 0.12% users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of the chlorhexidine gluconate oral rinse USP, 0.12% users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from the use of PerioGard® does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion

should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from PerioGard® treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.

3. Some patients may experience an alteration in taste perception while undergoing treatment with a chlorhexidine gluconate oral rinse USP, 0.12%. Rare instances of permanent taste alteration following chlorhexidine gluconate oral rinse USP, 0.12% use have been reported via postmarketing product surveillance.

Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 mL (2 doses) of PerioGard® per day.

Pediatric Use

Clinical effectiveness and safety of PerioGard® have not been established in children under the age of 18.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian *in vivo* mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS

The most common side effects associated with chlorhexidine gluconate oral rinse USP, 0.12% are: (1) an increase in staining of teeth and other oral surfaces, (2) an increase in

calculus formation, and (3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse. The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1.0%.

Among postmarketing reports, the most frequently reported oral mucosal symptoms associated with chlorhexidine gluconate oral rinse USP, 0.12% are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine gluconate oral rinse.

There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using chlorhexidine gluconate oral rinse.

OVERDOSAGE

Ingestion of 1 or 2 ounces of PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) by a small child (~10 kg body weight) might result in gastric distress, including nausea. Medical attention should be sought if more than 4 ounces of PerioGard® Oral Rinse is ingested by a small child.

DOSAGE AND ADMINISTRATION

PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) therapy should be initiated directly following a dental prophylaxis. Patients using PerioGard® should be reevaluated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 1/2 fl. oz. ("15 mL" line in dosage cap) of undiluted PerioGard®. Patients should be instructed not to rinse with water or other mouthwashes, brush teeth, or eat immediately after using PerioGard®. PerioGard® is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED

PerioGard® is supplied as a blue liquid in a 16-fluid ounce (473 mL) (NDC 0126-0282-16) amber plastic bottle with child-resistant dosage cap.

Store at 20° to 25°C (68° to 77°F) excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Rx Only. Keep out of reach of children.

Colgate Oral Pharmaceuticals, Inc.,
a subsidiary of Colgate-Palmolive Company
New York, NY 10022 U.S.A.
Questions/Comments: 1-800-962-2345
www.colgateprofessional.com

Revised: December 2019

To open child safety cap, squeeze smooth sides while turning. To close, turn until cap stops.

DIRECTIONS FOR USE: *Fill cap to the fill line (15 mL). Swish in mouth undiluted for 30 seconds, then* ***spit out****. Use after breakfast and before bedtime. Or, use as prescribed.*

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, propylene glycol, glycerin, sorbitol, polyoxyl 40 hydrogenated castor oil, flavor, cetylpyridinium chloride, and FD&C blue no. 1.

WHAT TO EXPECT WHEN USING PERIOGARD® (CHLORHEXIDINE GLUCONATE ORAL RINSE USP, 0.12%): Your dentist has prescribed PerioGard® (Chlorhexidine Gluconate Oral Rinse USP, 0.12%) to treat your gingivitis, to help reduce the redness and swelling of your gums, and also to help you control any gum bleeding. Use PerioGard® regularly, as directed by your dentist, in addition to daily brushing and flossing. Spit out after use; PerioGard® should not be swallowed.

If you develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, lightheadedness, rapid heart rate, upset stomach or diarrhea, seek medical attention immediately. PerioGard® should not be used by persons who have a sensitivity to it or its components.

PerioGard® may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months, or more frequently if your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. PerioGard® may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- PerioGard® may taste bitter to some patients and can affect how foods and beverages taste. This will become less noticeable in most cases with continued use of PerioGard®.
- To avoid taste interference, rinse with PerioGard® after meals. Do not rinse with water or other mouthwashes immediately after rinsing with PerioGard®.

If you have any questions or comments about PerioGard®, contact your dentist, pharmacist or Colgate toll free at: 1-800-962-2345.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Rx Only. Keep out of reach of children.

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Revised: December 2019

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

Colgate®

NDC 0126-0282-16

PerioGard®
(Chlorhexidine Gluconate
Oral Rinse USP, 0.12%)

ALCOHOL FREE

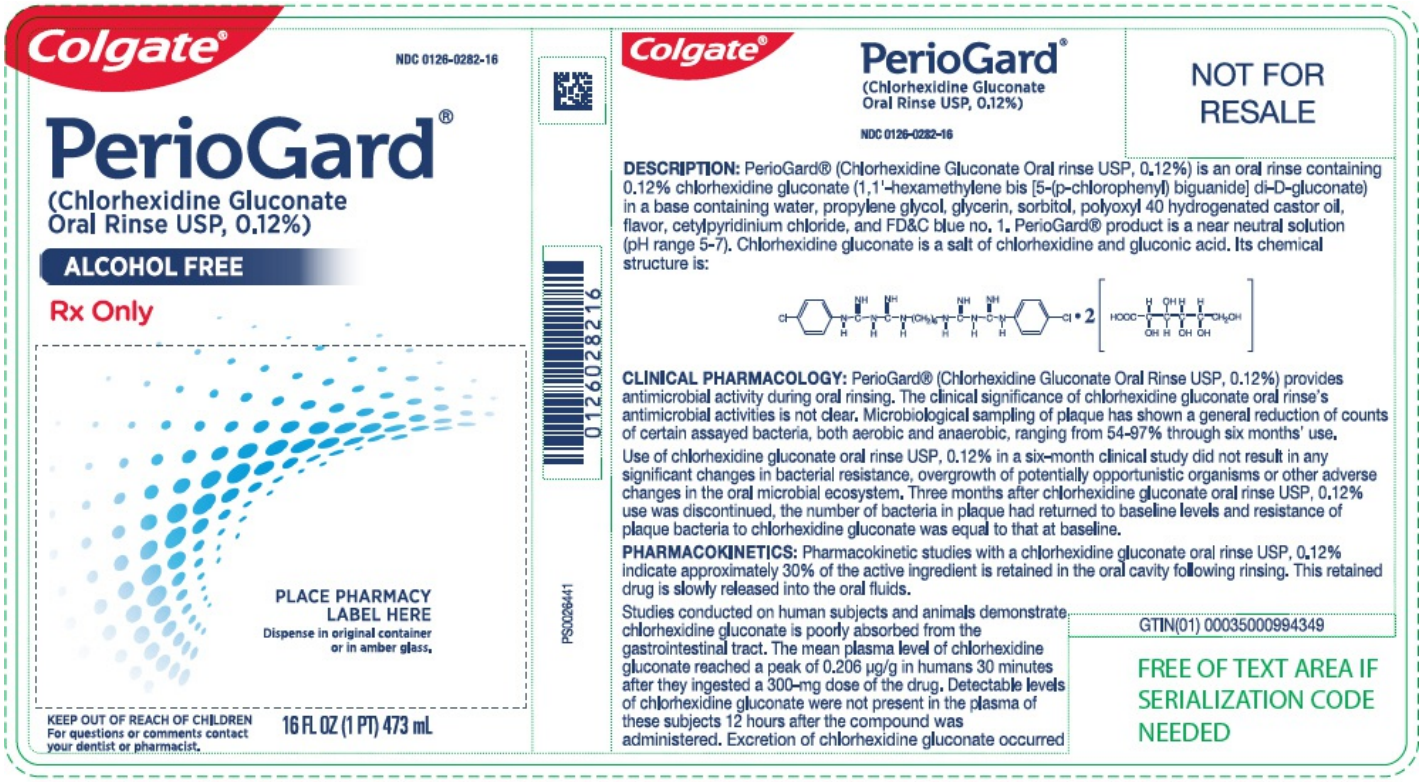
Rx Only

PLACE PHARMACY
LABEL HERE

Dispense in original container
or in amber glass.

KEEP OUT OF REACH OF CHILDREN
For questions or comments contact
your dentist or pharmacist.

16 FL OZ (1 PT) 473 mL



PERIOGARD ALCOHOL FREE

chlorhexidine gluconate rinse

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0126-0282
Route of Administration	BUCCAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	BLUE (Clear, light blue fluid)	**Score**	
Shape		**Size**	
Flavor	PEPPERMINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0126-0282-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203212	10/04/2021	

Labeler - Colgate Oral Pharmaceuticals, Inc. (968801118)