

Colgate
PERIOGARD (Chlorhexidine Gluconate Oral Rinse 0.12%)

Before prescribing, please consult the package insert. Below is a brief summary of that insert.

DESCRIPTION: PERIOGARD (Chlorhexidine Gluconate Oral Rinse 0.12%) is an oral rinse containing 0.12% chlorhexidine gluconate [N, N'-bis (4-chlorophenyl)-3, 12-diimino-2,4,11,13-tetraazatetradecanedimidamide di-D-gluconate] in a base containing water, 11.6% alcohol (%v/v), glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin, and FD&C Blue No. 1. PERIOGARD is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconate acid, with a molecular formula of $C_{22}H_{30}Cl_2N_{10}O_7$ and a molecular weight calculated to be 897.77.

INDICATIONS AND USAGE: PERIOGARD 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.

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 compared with control users. It is not known if chlorhexidine gluconate use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months.

Rare hypersensitivity and generalized allergic reactions have also been reported. PERIOGARD should not be used by persons who have a sensitivity to it or its components.

PRECAUTIONS

GENERAL:

1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with PERIOGARD 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 toothstaining. In clinical testing, 56% of the chlorhexidine gluconate oral rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of the chlorhexidine gluconate 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. Most patients accommodate to this effect with continued use of PERIOGARD. No instances of permanent taste alteration due to the use of a chlorhexidine gluconate oral rinse have been reported.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:

In a drinking water study in rats, carcinogenesis was not observed. The highest dose of chlorhexidine gluconate used in this study, 38 mg/kg/day, is at least 500 times the amount that would be ingested from the recommended daily dose of PERIOGARD.

In two mammalian in vivo mutagenic studies with chlorhexidine gluconate, mutagenesis was not observed. The highest dose of chlorhexidine gluconate used in a mouse dominant lethal assay was 1000 mg/kg/day and in a hamster cytogenetics test was 250 mg/kg/day, i.e. > 3200 times the amount that would be ingested from the recommended daily dose of PERIOGARD.

PREGNANCY: Pregnancy Category B. Reproduction and fertility studies with chlorhexidine gluconate have been conducted. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day, and no evidence of harm to the fetus was observed in rats and rabbits at doses up to 300 mg/kg/day and 40 mg/kg/day, respectively. These doses are approximately 100, 300, and 40 times that which would result from a person's ingesting 30 mL of PERIOGARD per day. Since controlled studies in pregnant women have not been conducted, the benefits of the drug in pregnant women should be weighed against the possible risk to the fetus.

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 is administered to a nursing woman.

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 capfuls) of PERIOGARD per day.

PEDIATRIC USE: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS: The most common side effects associated with chlorhexidine gluconate oral rinses 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. No serious systemic adverse reactions associated with use of a 0.12% chlorhexidine gluconate oral rinse were observed in clinical testing.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine gluconate oral rinses, particularly among children.

Although there have been no reports of parotitis (inflammation or swelling of the salivary glands) among the users of chlorhexidine gluconate oral rinse in controlled clinical studies, transient parotitis has been reported in research studies with chlorhexidine-containing mouthrinses.

OVERDOSAGE: Ingestion of 1 or 2 ounces of PERIOGARD by young or small pediatric patients (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of PERIOGARD is ingested by young or small pediatric patients if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: PERIOGARD 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. (marked on dosage cup) of undiluted PERIOGARD. PERIOGARD is not intended for ingestion and should be expectorated after rinsing.

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Manufactured for Colgate Oral Pharmaceuticals by PACO Pharm., Lakewood, NJ 08701

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Worldwide leader in oral care.

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tion due to the relatively short setting time of this 4-META product, and the potential for a more hurried condensation exists.

Other concerns are the pooling of these resins creating voids under amalgams and possible long-term breakdown of these products in an aqueous environment. With probable future improvements in these products, such as reduction of film thickness, increased working time and a reduction in cost, these materials will likely be the new generation of cavity sealers.

The 4-META products have been successfully used as luting agents in Japan for over 10 years, but improvements in the product are needed before they can be used routinely in the place of cavity varnish under amalgam restorations.

**James E. Newman Jr.,
 LTC DE
 Ft. Bragg, N.C.**

DENTAL BILLS

I would like to add my support for Drs. Spencer Redding and Raymond Garrison in their response to Dr. Gordon Christensen regarding "How Should Dental Bills be Paid?" (July 1994 JADA). Maybe if Dr. Christensen would apply some research thoroughness (as he so well does for dental materials and equipment), he would come to a different conclusion.

I practice in a rural area of North Carolina with a high poverty rate (35 percent are on welfare) where 46 percent of our babies are born out of wedlock to very young mothers. (This social dilemma is out of control and indeed should be addressed; this, however, is not the purpose of this letter.) The point I wish to make is that we

have many children who are suffering—as well as adults and the elderly—and who have no means of payment for dental care other than Medicaid.

Dr. Christensen, I'm sure Dr. Garrison would support me in saying that Medicaid reimbursement is so low that our costs are not covered. This problem is so great that I cannot find a pedodontist to accept my referrals for rampant caries in my 2- to 6-year-old patient population. In my practice, I average seeing at least two patients per week who need to be hospitalized for their dental needs. Until you have performed a full-mouth extraction in your office on a 4-year-old as I have done, maybe you should reconsider your stance regarding well-funded public support for dental care.

Dr. Christensen also suggested that I see a few patients at no charge. In order to do my part, I would have to provide 40 to 50 percent of my services at no charge. How can I survive when my fees are 15 to 20 percent below the national average and my paying patients and their insurance companies complain that my fees are too high?

Dr. Christensen, please come to my area and do some research before you do more damage to your excellent reputation and that of CRA.

**C. Douglas Peedin Jr.,
D.D.S.
Roanoke Rapids, N.C.**

Author's response: The situation Dr. Peedin described is in-

deed deplorable. Undoubtedly, there are some other areas such as the one he described in our great country. Early in my career, I spent several months in the rural Appalachian area and found the conditions he described. In my article entitled "How Should Dental Bills be Paid?" I described the typical, average situation encountered in the United States. That is not the situation he described.

I have empathy for the condition in the area in which he lives. It appears that the problem described is much more involved than dental therapy. I wish the government leaders and Dr. Peedin success in finding a solution to the overall social problems in his area.

**Gordon Christensen,
D.D.S., Ph.D.
CRA Oral Health Institute
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SLEEP APNEA

Thank you for publishing Dr. Osseiran's study on an intraoral appliance for obstructive sleep apnea (April JADA). It lends credibility and fosters interest in an underutilized, high-benefit/low-cost treatment that should be a part of every office.

We first began experimenting with vacuum-pressed, dual-splint designs in the mid '80s in an attempt to make an appliance that was less expensive, clasped all teeth uniformly and comfortably (without abrasive metal) and was minimally invasive, yet could easily be reset to allow for

positional changes. One version was published in 1988.

Since then, we have found that with little modification, one can successfully treat partially and totally edentulous arches and other difficult cases (relapse of previous pharyngoplasty, children). With Pierre Robin, we believe that compromised breathing reaches to the core of human development and personality, including various forms of depression, impotence, child nocturnal enuresis, learning disorders and altered physical development.

Though an oral appliance is appropriate in a portion of these cases, dentists and hygienists can readily identify many tell-tale clues and make referrals to other members of the medical-dental team (ear, nose and throat specialist; neurologist; allergist; etc.) for diagnosis and collaboration on treatment.

Over the years, dentists learn to give themselves strokes for the commonly underappreciated "job well done," but it will make your day when a patient drops by to report that his Apnea Index went from 29 desats/hour to 0 with his appliance and then relates all the new things he does with his newfound stamina.

I look forward to reading more from Dr. Osseiran and others on this subject.

**Darick Nordstrom, D.D.S.
Hollister, Calif.**