INDICATION: Peridex Oral Rinse 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 gingiva, including gingival bleeding upon probing. Peridex Oral Rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis, patients should be excluded from Peridex Oral Rinse 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.

CLINICAL PHARMACOLOGY: Peridex Oral Rinse provides antimicrobial activity during oral rinsing. The clinical significance of Peridex 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, which were present in plaque through six months of use. Furthermore, Peridex Oral Rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially harmful organisms or other adverse changes in the oral microbial ecosystem. Three months after Peridex Oral Rinse use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine glucostate was equal to that at baseline.

PHARMACOKINETICS: Pharmacokinetic studies with Peridex Oral Rinse have been performed in areas which begin to discolor.

CONTRAINDICATIONS: Peridex Oral Rinse should not be used by persons who are known to be hypersensitive to chlorhexidine glucostate or other formula ingredients.

WARNINGS: The effect of Peridex Oral Rinse on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Peridex Oral Rinse users compared with control users. It is not known if Peridex Oral Rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Hypersensitivity and generalized allergic reactions have occurred. SEE CONTRAINDICATIONS.

PRECAUTIONS: General:
1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Peridex Oral Rinse should not be used as a basis which begins to discolor.

ADVERSE REACTIONS: The most common side effects associated with chlorhexidine glucostate 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. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine glucostate 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 post marketing reports, the most frequently reported oral mucosal symptoms associated with Peridex Oral Rinse are: stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesis, glossal edema, and parapharyngitis.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using Peridex Oral Rinse.

There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using Peridex Oral Rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of Peridex Oral Rinse by a small child (<1kg body weight) might result in gastric distress, signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of Peridex Oral Rinse is ingested by a small child or signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: Peridex Oral Rinse therapy should be initiated directly following a dental prophylaxis. Patients using Peridex Oral Rinse should be reevaluated and given a thorough prophylaxis at intervals not greater than six months.

HOW SUPPLIED: Peridex Oral Rinse is supplied as a blue liquid in:
• 16 fl. oz. (473ml) (NDC 51284-620-22) ambar plastic bottles with child resistant dispensing closures
• 4 fl. oz. (118ml) (NDC 51284-620-12) ambar plastic bottles with child resistant dispensing closures
• 64 oz. (NDC 51284-620-32) white plastic bottle with pump dispensing closure

DIRECTIONS FOR USE: Swish 15ml (one tablespoon) rinsed 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.

WHAT TO EXPECT WHEN USING PERIDEX ORAL RINSE: Peridex Oral Rinse is prescribed to treat gingivitis, to help reduce plaque formation, to help prevent the formation of tartar, and to help control any gum bleeding. Peridex Oral Rinse should be used regularly as directed by a dentist, in addition to daily brushing. Peridex should be spit out after use. It should not be swallowed.

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

• Both stain and tartar can be removed by your dentist or hygienist. Peridex Oral Rinse may cause permanent discoloration of some front-tooth fillings.
• To minimize discolorization, you should brush and floss daily, using a dentifrice which has a weak discoloring effect.
• Local hypersensitivity and sometimes generalized allergic reactions have also been reported. Peridex Oral Rinse should not be used by persons who have a sensitivity to it or its components.
• Peridex Oral Rinse 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 Peridex Oral Rinse.
• To avoid taste interference, rinse with Peridex Oral Rinse after meals. Do not rinse with water or other mouthwashes immediately after rinsing with Peridex Oral Rinse.

If you have any questions or comments about Peridex Oral Rinse, contact your dentist or pharmacist.

STORE ABOVE FREEZING (32°F or 0°C) Caution: Federal law prohibits dispensing without prescription.