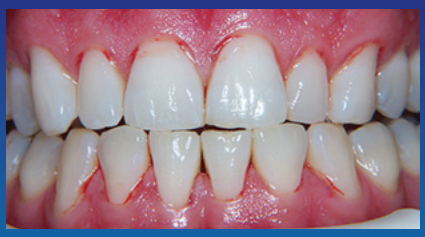
3M Science. Applied to Life.™

Powerful combination for the long run.

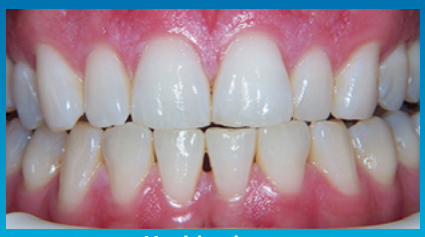
Peridex™
Chlorhexidine Gluconate
0.12% Oral Rinse

PerioMed™
0.63% Stannous Fluoride
Oral Rinse Concentrate

Chronic inflammation and bleeding can be indicators of gingivitis or even more severe oral health issues. These infections require professional treatment to reverse the disease and prevent it from recurring.



Gingivitis
(bleeding on brushing/flossing)



Healthy tissue

Peridex™ Chlorhexidine Gluconate 0.12% Oral Rinse

Peridex™ is an effective oral rinse 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. Supported by more than 20 years of clinical proof, Peridex oral rinse:

- provides antimicrobial activity during oral rinsing
- reduces certain aerobic and anaerobic bacteria from 54–97% through six months of use
- reduces gingival inflammation and bleeding between dental visits, including those for operative procedures
- shows no significant changes in bacterial resistance or adverse changes in the oral microbial ecosystem
- has a 2-year shelf life

PerioMed™ 0.63% Stannous Fluoride Oral Rinse Concentrate

Follow up with PerioMed™ oral rinse for long-term gingival maintenance therapy. A proven aid to help control plaque bacteria, PerioMed oral rinse:

- is a second-generation anti-microbial
- is a non-alcohol formula
- costs about the same as the leading OTC mouthwashes[1]
- is available in Mint and Tropical Fruit flavors

Some oral rinses, including these, may cause enamel discoloration. Advise your patients that this discoloration will be more pronounced in areas with heavier accumulations of plaque and can be minimized by brushing and flossing daily. Discoloration can be removed from most tooth surfaces with prophylaxis treatment.

The benefits of these time-tested, clinically proven medications are clear. Start your patients on Peridex chlorhexidine gluconate 0.12% oral rinse and follow up with PerioMed 0.63% stannous fluoride oral rinse ... a powerful combination for long-term oral care.

The clinical significance of Peridex oral rinse's antimicrobial activities is not clear. 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 gluconate was equal to that at baseline. Clinical effectiveness and safety of Peridex oral rinse has not been established in children under age 18.

Peridex oral rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis. Patients with a known sensitivity to chlorhexidine gluconate should not use Peridex oral rinse. The effect of Peridex oral rinse on periodontitis has not been determined. Common side effects associated with the use of Peridex oral rinse include an increase in the staining of oral surfaces, an increase in calculus formation and an alteration in taste perception. Please see back page for full prescribing information.

1. Data on file.

Proven Effective.

+

Peridex™ Chlorhexidine Gluconate 0.12% Oral Rinse is available in 4oz, 16oz and 64oz sizes.

PerioMed™ 0.63% Stannous Fluoride Oral Rinse Concentrate is available in Mint and Tropical Fruit Flavors.

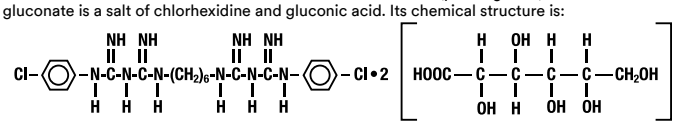
Ordering Information

Item #	Product Description
12134	Peridex™ Chlorhexidine Gluconate 0.12% Oral Rinse — 4 oz bottle (48 bottles/case)
12132	Peridex™ Chlorhexidine Gluconate 0.12% Oral Rinse — 16 oz bottle (12 bottles/case)
12133	Peridex™ Chlorhexidine Gluconate 0.12% Oral Rinse — 64 oz bottle (4 bottles/case)
12105M	PerioMed™ 0.63% Stannous Fluoride Oral Rinse Concentrate — Mint Flavor — 10 oz bottle with pump (24 bottles/case)
12105F	PerioMed™ 0.63% Stannous Fluoride Oral Rinse Concentrate — Tropical Fruit Flavor — 10 oz bottle with pump (24 bottles/case)
12105SM	PerioMed™ 0.63% Stannous Fluoride Oral Rinse Concentrate — Mint Flavor — 2.75 oz bottle with mixing cup (24 bottles/case)

Peridex™
Chlorhexidine Gluconate 0.12% Oral Rinse

INDICATION: Peridex™ Chlorhexidine Gluconate 0.12% 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 gingivae, including gingival bleeding upon probing. Peridex oral rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG).
For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

DESCRIPTION: Peridex oral rinse is an oral rinse containing 0.12% chlorhexidine gluconate (1, 1¹-hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Peridex oral rinse 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: 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, ranging from 54-97% through six months use. Use of Peridex oral rinse in a six month clinical study did not result in any significant changes in bacteria resistance, overgrowth of potentially opportunistic 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 gluconate was equal to that at baseline.

PHARMACOKINETICS: Pharmacokinetic studies with Peridex oral rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, 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 0.206µg/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.

CONTRAINDICATIONS: Peridex oral rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate 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. 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 Peridex oral rinse should not be used as a major indicator of underlying periodontitis.
2. Peridex oral rinse 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 Peridex oral rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of Peridex oral rinse 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 use of Peridex oral rinse 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 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.
3. Some patients may experience an alteration in taste perception while undergoing treatment with Peridex oral rinse. Rare instances of permanent taste alteration following Peridex oral rinse use have been reported via post-marketing product surveillance.

PREGNANCY: TERATONGENIC 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 Peridex oral rinse 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 capfuls) of Peridex oral rinse per day.

PEDIATRIC USE: Clinical effectiveness and safety of Peridex oral rinse 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 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 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 post marketing reports, the most frequently reported oral mucosal symptoms associated with Peridex oral rinse 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 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 (~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 Peridex oral rinse is ingested by a small child or if 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 no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 15 ml (marked in cap) of undiluted Peridex oral rinse. Patients should be instructed to not rinse with water or other mouthwashes, brush teeth or eat immediately after using Peridex oral rinse. Peridex oral rinse is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED: Peridex oral rinse is supplied as a blue liquid in the following sizes:
- 0.5 fluid ounce (15 ml) (NDC 48878-0620-4) amber plastic bottle with child-resistant dispensing closure
- 4 fl ounce (118 ml) (NDC 48878-0620-3) amber plastic bottles with child-resistant dispensing closure
- 16 fl ounce or 1 pint (473ml) (NDC 48878-0620-1) amber plastic bottles with child-resistant dispensing closure
- 64 fluid ounce (1893 ml) (NDC 48878-0620-2) white plastic bottle with pump dispensing closure

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

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

Peridex 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. Peridex may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- Peridex 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.
- To avoid taste interference, rinse with Peridex after meals. Do not rinse with water or other mouthwashes immediately after rinsing with Peridex.

If you have any questions or comments about Peridex, contact your dentist or pharmacist, or 3M ESPE Dental Products toll free at 1-800-634-2249.

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

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled room temperature].

Rx only

KEEP OUT OF REACH OF CHILDREN

Made in U.S.A. for:
3M ESPE
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Revised: January 2015

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