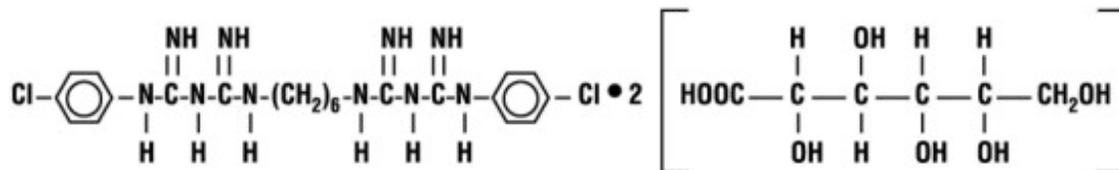


PERIDEX- chlorhexidine gluconate rinse
3M ESPE Dental Products

Peridex™ (Chlorhexidine Gluconate 0.12%) Oral Rinse

DESCRIPTION

Peridex™ (Chlorhexidine Gluconate 0.12%) 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 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 provides antimicrobial activity during oral rinsing. The clinical significance of Peridex'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 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 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 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.

INDICATIONS AND USAGE

Peridex 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 has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

CONTRAINDICATIONS

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

WARNINGS

The effect of Peridex on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in Peridex users compared with control users. It is not known if Peridex 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 should not be used as a major indicator of underlying periodontitis.
2. Peridex 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 users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of Peridex 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 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 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. Rare instances of permanent taste alteration following Peridex use have been reported via post-marketing product surveillance.

Pregnancy

Teratogenic Effects

Pregnancy Category B

Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300mg/kg/day and 40mg/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 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 30ml (2 capfuls) of Peridex per day.

Pediatric Use

Clinical effectiveness and safety of Peridex 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 38mg/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 1000mg/kg/day and 250mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100mg/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 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. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using Peridex.

OVERDOSAGE

Ingestion of 1 or 2 ounces of Peridex 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 is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION

Peridex therapy should be initiated directly following a dental prophylaxis. Patients using Peridex 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 15ml (marked in cap) of undiluted Peridex. Patients should be instructed to not rinse with water or other mouthwashes, brush teeth or eat immediately after using Peridex. Peridex is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED

Peridex 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 fluid ounce (118 ml) (NDC 48878-0620-3) amber plastic bottles with child resistant dispensing closure

16 fluid 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

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

**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, 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.

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[See USP controlled room temperature].**

Revised: January/2013

Made in U.S.A. for:
3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 U.S.A.

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Principal Display Panel – Bottle Label

NDC 48878-0620-1

Peridex™

(CHLORHEXIDINE GLUCONATE 0.12%)

ORAL Rinse

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.

Rx only

KEEP OUT OF REACH OF CHILDREN

PLACE DISPENSING
INFORMATION HERE

Dispense in bottle as
provided or in amber glass

REF 12132 1 Pint (473ml)

3M ESPE I.D. No.

70-2010-5520-2

3M ESPE



NDC 48878-0620-1
PERIDEX™
(CHLORHEXIDINE GLUCONATE 0.12%)
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Dispense in bottle as
provided or in amber glass

REF 12132
3M ESPE I.D. No.
70-2010-5520-2

1 Pint (473ml)
3M ESPE

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diostearate, flavor, sodium saccharin and FD&C Blue No.1.
To Open: Squeeze smooth areas near bottom of cap and turn. To Close: Turn cap until it locks.

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Revised: January 2013

Made in U.S.A. for:
3M ESPE Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

PERIDEX

chlorhexidine gluconate rinse

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48878-0620
Route of Administration	ORAL	DEA Schedule	

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
glycerin (UNII: PDC6A3C0OX)	
saccharin sodium (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
water (UNII: 059QF0K00R)	
alcohol (UNII: 3K9958V90M)	

Product Characteristics

Color	blue (blue)	Score	
Shape		Size	
Flavor	MINT (MINT)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48878-0620-4	15 mL in 1 BOTTLE		
2	NDC:48878-0620-3	118 mL in 1 BOTTLE		
3	NDC:48878-0620-1	473 mL in 1 BOTTLE		
4	NDC:48878-0620-2	1893 mL in 1 BOTTLE, DISPENSING		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019028	08/13/1986	

Labeler - 3M ESPE Dental Products (799975909)

Revised: 1/2013

3M ESPE Dental Products