

Product Monograph
Including Patient Medication Information

 **PERIDEX® ORAL RINSE**

Chlorhexidine Gluconate Oral Rinse 0.12%
Antigingivitis Oral Rinse

Solventum Canada Limited
400 Route 100
Morden, Manitoba, R6M 1Z9, Canada

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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

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Part 1: Healthcare Professional Information

1. Indications

Peridex Oral Rinse (0.12% chlorhexidine gluconate) is indicated for use as part of a professional program for the treatment of moderate to severe gingivitis, and for management of associated gingival bleeding and inflammation between dental visits. For patients having coexisting gingivitis and periodontitis, see [7 Warnings and Precautions](#).

1.1. Pediatrics

Pediatrics (under 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

2. Contraindications

Peridex Oral Rinse is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see [6 Dosage Forms, Strengths, Composition, and Packaging](#).

4. Dosage and Administration

4.1. Dosing Considerations

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; they should be referred for periodontal consultation as necessary.

4.2. Recommended Dose and Dosage Adjustment

Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after tooth brushing. Usual dosage is 15 mL (marked in cap) of undiluted Peridex Oral Rinse. Peridex Oral Rinse is not intended for ingestion and should be expectorated after rinsing. The suggested initial course of therapy is 3 months, at which time patients should be recalled for evaluation.

Health Canada has not authorized an indication for pediatric use.

4.4. 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; they should be referred for periodontal consultation as necessary.

Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after tooth brushing. Usual dosage is 15 mL (marked in cap) of undiluted Peridex Oral Rinse. Peridex Oral Rinse is not intended for ingestion and should be expectorated after rinsing. Rinsing the mouth (with water or other mouthwashes), brushing teeth, or eating or drinking should be avoided for about 30 minutes after using Peridex Oral Rinse.

The suggested initial course of therapy is 3 months, at which time patients should be recalled for

evaluation. At the time of the recall visit, the dental professional should:

- Evaluate progress, remove any stain, and reinforce proper home care techniques.
- If gingival inflammation and bleeding is controlled, discontinue Peridex Oral Rinse therapy and recall the patient in three months to assess gingival health.
- If gingival inflammation and bleeding persist, continue Peridex Oral Rinse therapy for an additional 3 months and schedule a three-month recall for evaluation.
- Evaluate for evidence of epithelial irritation, desquamation and parotitis.

The following generally accepted grading scheme may be of use in evaluating the severity of gingivitis.

Table 1. Loe and Silness gingival index

Grade	Description
1	Normal gingival, no inflammation, no discolouration, no bleeding
2	Mild inflammation, slight colour change, mild alteration of gingival surface. No bleeding
3	Moderate inflammation, erythema, swelling, bleeding on probing or when pressure applied.
4	Severe inflammation, severe erythema and swelling, tendency toward spontaneous haemorrhage, some ulceration.

4.5. Missed Dose

An occasional missed dose can be ignored if the patient is generally compliant with the prescribed regimen.

5. Overdose

Ingestion of 30 or 60 mL of Peridex Oral Rinse by a small child (10 kg or less body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 120 mL of Peridex Oral Rinse is ingested by a small child or signs of alcohol intoxication develop.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 2. Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
oral	Liquid, 475 mL	alcohol, FD&C Blue #1 Dye, glycerine, flavour, PEG-40 sorbitan di-isostearate, saccharin sodium, water

Description

Peridex Oral Rinse is supplied as a blue liquid in 475 mL amber plastic bottles with child-resistant dispensing closures.

7. Warnings and Precautions

General

For patients having coexisting gingivitis and periodontitis, the absence of gingival inflammation following treatment with Peridex Oral Rinse may not be indicative of the absence of underlying periodontitis. Appropriate treatment of periodontitis is therefore indicated.

Peridex Oral Rinse may cause staining of oral surfaces such as the film on tooth surfaces, restorations, and the dorsum of the tongue. Stain will be more pronounced in patients who have heavier accumulations of un-removed plaque. Stain resulting from use of Peridex Oral Rinse does not adversely affect the health of gingivae or other oral tissue. 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 treating patients with exposed root surfaces or anterior facial restorations with rough surfaces or margins. If natural stains cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from Peridex Oral Rinse treatment if the risk of permanent discolouration is unacceptable. Stains in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.

A few patients may experience an alteration in taste perception while undergoing treatment with Peridex Oral Rinse. Most of these patients accommodate to this effect with continued use of Peridex Oral Rinse. Rare instances of permanent taste alteration following Peridex Oral Rinse use have been reported via post-marketing product surveillance.

For maximum effectiveness the patient should avoid rinsing their mouth (with water or other mouthwashes), brushing their teeth, eating or drinking for about 30 minutes after using Peridex Oral Rinse.

Carcinogenesis and Genotoxicity

No evidence of carcinogenicity was reported in two rat studies in which chlorhexidine was administered in their drinking water. The studies were two years in duration and delivered chlorhexidine at dose levels of up to 200 mg/kg/day.

Reproductive Health

No adverse reproductive or teratologic effects on rats or rabbits were observed in studies with the mouth rinse formulation.

The effect of chlorhexidine gluconate on various aspects of reproductive processes has been evaluated using both the rat and rabbit as a model. An apparent embryotoxic effect was observed in rabbits that received a daily 40 mg/kg dose of chlorhexidine by gavage and in rats that ingested a 300 mg/kg dose of chlorhexidine from their diet each day. These doses are about 140 and 1040 times, respectively, the estimated daily ingestion from Peridex Oral Rinse with the recommended dose.

- **Fertility**

Reproduction and fertility studies with chlorhexidine gluconate have been conducted. No evidence of impaired fertility was observed in male and female 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 ingesting 30 mL (2 capfuls) of Peridex Oral Rinse per day.

Sensitivity/Resistance

A variety of regimens were used in an attempt to induce and elicit immediate hypersensitivity to chlorhexidine gluconate in guinea pigs, rabbits, rats and man. No evidence of immediate hypersensitivity was observed in any of the tests.

7.1. Special Populations

7.1.1. Pregnancy

Reproduction and fertility studies with chlorhexidine gluconate have been conducted. No evidence of impaired fertility was observed in male and female 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 ingesting 30 mL (2 capfuls) of Peridex Oral Rinse per day. Since controlled studies in pregnant women have not been conducted, the benefits of use of the drug in pregnant women should be weighed against possible risk to the fetus.

7.1.2. Breastfeeding

It is not known whether this drug is excreted in human milk. 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 the dose which would result if a person ingested the entire recommended dose of Peridex Oral Rinse on a daily basis.

7.1.3. Pediatrics

Pediatrics (under 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

8. Adverse Reactions

8.1. Adverse Reaction Overview

The most common side effects associated with chlorhexidine gluconate oral rinse are (1) an increase in staining of oral surfaces, (2) an increase in supragingival tartar (3) an alteration in taste perception to which most patients accommodate (see [7 Warnings and Precautions](#)).

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the frequencies of adverse reactions observed in the clinical trials may not reflect frequencies observed in clinical practice and

should not be compared to frequencies reported in clinical trials of another drug.

No serious systemic reactions associated with use of Peridex Oral Rinse were observed in clinical testing. However, some adverse reactions have been reported in studies with Peridex Oral Rinse or other chlorhexidine-containing mouth rinses. The most common side effects associated with chlorhexidine gluconate oral rinse are (1) an increase in staining of oral surfaces, (2) an increase in supragingival tartar (3) an alteration in taste perception to which most patients accommodate (see [Warnings and Precautions](#)).

Epithelial irritation and superficial desquamation of the oral mucosa have been noted in studies of children using 0.12% chlorhexidine gluconate which were reversible upon discontinuation.

There have been rare cases of parotid gland swelling and inflammation of the salivary glands, in patients using Peridex Oral Rinse.

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, ulcerations, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocoele, and short frenum. Each occurred at a frequency of less than 1.0%.

8.5. Post-Market Adverse Reactions

Among postmarketing 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.

9. Drug Interactions

9.2. Drug Interactions Overview

Peridex Oral Rinse is not to be mixed/diluted with any other product.

9.5. Drug-Food Interactions

Peridex Oral Rinse may taste bitter to some patients and may affect the taste of foods and beverages. 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 mouth rinses immediately after rinsing with Peridex Oral Rinse.

For maximum effectiveness avoid rinsing your mouth, brushing your teeth, eating or drinking for about 30 minutes after using Peridex Oral Rinse.

10. Clinical Pharmacology

10.1. Mechanism of Action

0.12% chlorhexidine gluconate provides antimicrobial activity during oral rinsing which is maintained between rinsings. Microbiologic sampling of plaque has shown a general reduction of both aerobic and anaerobic bacterial counts ranging from 54-97% through six months of clinical use. Rinsing with 0.12% chlorhexidine gluconate inhibits the buildup and maturation of plaque by reducing certain microbes

regarded as gingival pathogens, thereby reducing gingivitis. 0.12% chlorhexidine gluconate provided antimicrobial activity during rinsing and for several hours thereafter.

10.2. Pharmacodynamics

Two clinical studies examined dose-response relationships and confirmed earlier animal studies. One short-term study demonstrated equal efficacy, as measured by plaque reduction, for 0.10% and 0.20% chlorhexidine gluconate solutions while a 0.05% chlorhexidine gluconate solution was less effective. In a three-month study, anti-gingivitis efficacy was equal for 0.12% and 0.20% chlorhexidine gluconate mouth rinses. However, tooth and tongue discolouration increases with chlorhexidine concentration in both studies. Therefore, the chlorhexidine gluconate concentration for Peridex Oral Rinse was set at 0.12% to optimize efficacy while minimizing side effects.

The effect of duration and frequency of rinsing on plaque formation and tooth and tongue discolouration was examined in another 88-day study. The data demonstrated that shorter, more frequent rinsing (i.e. 2 x 30 seconds) provided optimal efficacy as compared to longer, less frequent rinsing (i.e. 1 x 60 seconds).

10.3. Pharmacokinetics

Absorption

0.12% chlorhexidine gluconate is to be used topically as an oral rinse, not to be ingested. Studies were conducted to study its metabolic pathway in the event of oral ingestion.

Human studies using radiological markers indicated that chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. This is in agreement with the findings from animal studies. Among five normal male volunteers, gastrointestinal transit time was 31 to 53 hours as indicated by radio-opaque markers.

Distribution

Approximately 30% of the chlorhexidine present in the mouth rinse is retained in the oral cavity after rinsing. The amount retained was directly related to drug concentration, with an average of 6.3 and 2.7 mg (mean) of chlorhexidine being retained orally after a single use of a mouth rinse containing 0.12% and 0.06% chlorhexidine gluconate, respectively. The release rate of chlorhexidine from oral surfaces was similar for both treatments. Based on morning/evening rinses, previous exposure to a chlorhexidine-containing mouth rinse was observed to have little effect on subsequent retention of chlorhexidine.

Elimination

The primary route for the excretion of chlorhexidine was through the feces (approximately 90%). The mean peak plasma level of chlorhexidine was 0.206 mcg/g, reached 30 minutes after ingestion of a 300-mg dose of the drug. Chlorhexidine was not detectable in plasma 12 hours after ingestion. Urine samples contained 0.5 to 1% of the ¹⁴C-chlorhexidine gluconate administered to the study subjects.

11. Storage, Stability, and Disposal

Store above freezing temperature (0°C).

Part 2: Scientific Information

13. Pharmaceutical Information

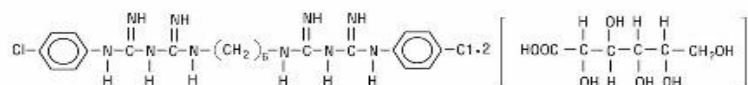
Drug Substance

Non-proprietary name of the drug substance(s): Chlorhexidine gluconate (U.S.A.N.)

Chemical name: 1,1'-hexamethylene bis [5- (p-chlorophenyl) biguanide] di-D-gluconate

Molecular formula and molecular mass: 897.8

Structure (for biologics)/Structural formula:



Product Characteristics:

Chlorhexidine has basic character and exists in the di-cationic form at physiologic pH. The two protonic positive charges become somewhat localized on the biguanide portion of the molecule. Both pKa's are reported as 10.78 ± 0.06 . The gluconate salt is soluble in excess of 70% (w/v) in water at 20°C.

At 19-21% w/v chlorhexidine gluconate solution is colourless to pale straw-coloured and is odourless to almost odourless (British Pharmacopoeia).

14. Clinical Trials

14.1. Clinical Trials by Indication

The efficacy of Peridex Oral Rinse in the treatment and prevention of gingivitis has been supported in three pivotal clinical trials and in several supporting studies. The pivotal clinical studies are summarized in the following chart:

Table 3. Summary of findings in pivotal clinical studies

Study Location	Study Duration	N	Age (years)	Sex	Usage Regimen ¹	Reduction in*		
						Plaque Index Scores	Gingival Inflammation Index Scores	Bleeding Sites
San Antonio TX.	3 months	597	18-60	M and F	15 mL twice daily	36.1%	27.8-45.8%	48.4%
Northfield, NJ	6 months	430	18-60			60.9%	33.5-45.4%	41.6-52.2%
London, ON	2 years	456	18-72			34.6-56.4%	39.6%	50.3%

N = Number of patients, M = males, F = females

¹ According to package label instructions

*Results shown are those obtained for the final examination at completion of test product use. The data are expressed as covariance adjusted % reduction vs. placebo; a range is reported when there were duplicate examiners. All reductions were significantly different from placebo ($p < 0.05$; nonparametric Wilcoxon pair test)

The results of these studies confirm that Peridex Oral Rinse effectively reduces plaque buildup, the incidence and severity of gingivitis, as well as the number of bleeding areas.

15. Microbiology

In Vitro

Because of its nonspecific mechanism of action, chlorhexidine has a wide range of antimicrobial activity against both Gram-positive and Gram-negative bacteria. An in-vitro study of the microbicidal effect of Peridex Oral Rinse following a 30-second exposure resulted in greater than a 99.9% reduction in the following micro-organisms: *Actinomyces viscosus*, *Candida albicans*, *Staphylococcus aureus*, *Streptococcus mutans*, *Streptococcus sanguis*, *Fusobacterium nucleatum*, *Neisseria sicca*, *Pseudomonas aeruginosa*, *Veillonella parvula*.

In Vivo

To determine the efficacy of Peridex Oral Rinse in vivo, various bacteria in the microbial flora of plaque were assayed in subjects who had used either Peridex Oral Rinse or a placebo.

During six months of use of Peridex Oral Rinse, subjects showed reductions in total load/tooth, streptococci and actinomyces ranging from 54% to 97%. Neisseria and fusobacteria were not detected in over half of the subjects assayed. No changes in numbers of yeast-like organisms and Gram-negative enterics were observed. There were no adverse changes in the oral microbial flora. Three months following cessation of treatment, the reductions observed during mouth rinsing were no longer evident, indicating no “carryover” effect. The results were interpreted as indicating that the use of Peridex Oral Rinse was associated only with a decrease in the number of microbes in plaque and no change in bacterial sensitivity.

Another study was conducted to investigate whether changes occurred in resistance to chlorhexidine which might limit efficacy of the mouth rinse, and if such changes occurred, whether they dissipated or disappeared after cessation of use of the mouth rinse. Minimum inhibitory concentrations (MICs) for chlorhexidine were determined on isolates of streptococci and actinomyces obtained from patients during six months of use of the mouth rinse and three months after cessation of use of the mouth rinse. Changes in bacterial sensitivity due to exposure to chlorhexidine were slight, sporadic and had returned to pre-treatment values three months after product usage was discontinued.

These results support that Peridex Oral Rinse usage does not result in significant changes in plaque bacterial resistance and does not cause significant changes in the plaque flora.

16. Non-Clinical Toxicology

General toxicology

The oral lethal dose 50% (LD50) of chlorhexidine gluconate was estimated as 1.476 g/kg in rats and 0.1122 g/kg in rabbits. The oral LD50 of the mouth rinse formulation was estimated at > 20 g/kg in rats.

The only consistently observed finding in eight subchronic and chronic toxicity studies was the accumulation of foamy macrophages in the mesenteric lymph nodes of rats. Representative samples of these lesions were evaluated by two independent pathologists. They concluded that the lesions did not represent a significant toxic effect. This conclusion is supported by the following facts: 1) The macrophages do not contain bacteria, indicating that a significant change in the intestinal flora has not occurred. 2) The reaction is not associated with increased morbidity or mortality. 3) The reaction does not become progressively more severe with continued exposure to chlorhexidine. 4) The reaction is reversible after administration of chlorhexidine is discontinued.

No evidence of mutagenicity was observed when chlorhexidine gluconate was evaluated by the

dominant lethal assay in mice and micronucleus assay in hamsters. Mutagenicity studies, using bacterial cell system, with or without metabolic activation, produced contradictory results, which are unexpected with drugs having antibacterial activity. While Suessmuth et al. (1979) and Ackerman-Schmidt et al. (1982) obtained positive results, Evans et al. (1978) and Sakagami et al. (1988) found no evidence of genotoxicity for chlorhexidine. The clinical significance of these results is unclear.

A variety of regimens were used in an attempt to induce and elicit immediate hypersensitivity to chlorhexidine gluconate in guinea pigs, rabbits, rats and humans. No evidence of immediate hypersensitivity was observed in any of the tests.

The emetic dose, irritation potential, and sensitization potential have also been determined for Peridex Oral Rinse. Peridex Oral Rinse has an emetic median effective dose (ED50) of approximately 13.4 mL/kg (tested in dogs using the oral route of administration), is only slightly irritating to the eye (tested in rabbits), and was not irritating to the oral mucosa (tested in dogs). In addition, the mouth rinse does not induce delayed contact sensitization.

Carcinogenicity

No evidence of carcinogenicity was reported in two rat studies in which chlorhexidine was administered in their drinking water. The studies were two years in duration and delivered chlorhexidine at dose levels of up to 200 mg/kg/day.

Reproductive and developmental toxicology

No adverse reproductive or teratologic effects on rats or rabbits were observed in studies with the mouth rinse formulation.

The effect of chlorhexidine gluconate on various aspects of reproductive processes has been evaluated using both the rat and rabbit as a model. An apparent embryotoxic effect was observed in rabbits that received a daily 40 mg/kg dose of chlorhexidine by gavage and in rats that ingested a 300 mg/kg dose of chlorhexidine from their diet each day. These doses are about 140 and 1040 times, respectively, the estimated daily ingestion from Peridex Oral rinse with the recommended dose.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr PERIDEX® ORAL RINSE

Chlorhexidine Gluconate Oral Rinse 0.12%

Antigingivitis Oral Rinse

This Patient Medication Information is written for the person who will be taking PERIDEX® ORAL RINSE. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about PERIDEX® ORAL RINSE, talk to a healthcare professional.

What PERIDEX® ORAL RINSE is used for:

- Peridex (0.12% chlorhexidine gluconate) is indicated for use as part of a professional program for the treatment of moderate to severe gingivitis, and for management of associated gingival bleeding and inflammation between dental visits.

How PERIDEX® ORAL RINSE works:

Peridex Oral Rinse (0.12% Chlorhexidine Gluconate) provides antimicrobial activity during oral rinsing which is maintained between rinsings. Rinsing with Peridex inhibits the buildup and maturation of plaque by reducing certain microbes regarded as gingival pathogens, thereby reducing gingivitis. Peridex provided antimicrobial activity during rinsing and for several hours thereafter.

The ingredients in PERIDEX® ORAL RINSE are:

Medicinal ingredient(s): Chlorhexidine gluconate

Non-medicinal ingredients: alcohol, FD&C Blue #1 Dye, glycerine, flavour, PEG-40 sorbitan diisostearate, saccharin sodium, water

PERIDEX® ORAL RINSE comes in the following dosage form(s):

Peridex oral rinse (0.12% chlorhexidine gluconate) is supplied as a blue liquid in 475 mL amber plastic bottles with child-resistant dispensing closures.

Do not use PERIDEX® ORAL RINSE if:

- persons has a sensitivity to chlorhexidine gluconate
- patients are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PERIDEX® ORAL RINSE.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take PERIDEX® ORAL RINSE:

- Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after tooth brushing. Peridex is not intended for ingestion and should be expectorated after rinsing. Rinsing the mouth (with water or other mouthwashes), brushing teeth, or eating or drinking should be avoided for about 30 minutes after using Peridex.

Usual dose:

Usual dosage is 15 mL (marked in cap) of undiluted Peridex.

Overdose:

Ingestion of 30 or 60 mL of Peridex (0.12% chlorhexidine gluconate) by a small child (10 kg or less body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 120 mL of Peridex is ingested by a small child or signs of alcohol intoxication develop.

If you think you, or a person you are caring for, have taken too much PERIDEX® ORAL RINSE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

An occasional missed dose can be ignored if the patient is generally compliant with the prescribed regimen. If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

Possible side effects from using PERIDEX® ORAL RINSE:

These are not all the possible side effects you may have when taking PERIDEX® ORAL RINSE. If you experience any side effects not listed here, tell your healthcare professional.

Peridex may cause some tooth discolouration or increases in tartar (calculus) formation, particularly in areas where plaque is more difficult to remove with normal brushing alone. It is important to do a thorough job of cleaning your teeth and to see your dentist 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 discolouration of some front-tooth fillings. To minimize discolouration, you should brush and floss daily, emphasizing areas which begin to discolour. In some cases discolouration may be permanent.
- Peridex may taste bitter to some patients and may affect the taste of foods and beverages. 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 mouth rinses immediately after rinsing with Peridex.
- For maximum effectiveness avoid rinsing your mouth, brushing your teeth, eating or drinking for about 30 minutes after using Peridex.

Peridex oral rinse should not be used by persons who have a sensitivity to chlorhexidine gluconate. 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.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store above freezing (0°C).

If you want more information about PERIDEX® ORAL RINSE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](https://www.hc-sc.gc.ca/drugs/index-eng.php)); the manufacturer's website [<https://www.solventum.com/en-ca/home>]; or by calling 1-800-634-2249.

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