

PRODUCT MONOGRAPH

Pr **ORO CLEAR**[®]

Chlorhexidine Gluconate Oral Rinse, 0.12% w/v House Standard

Antigingivitis Oral Rinse

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ORO CLEAR

Chlorhexidine Gluconate Oral Rinse, 0.12% w/v House Standard

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
oral	0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard	None

For a complete listing, see Dosage Forms, Composition and Packaging section of the product monograph.

INDICATIONS AND CLINICAL USE

ORO CLEAR(0.12% w/v Chlorhexidine Gluconate oral rinse, House Standard) 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 according to the recommended dosage and frequency under supervision of a dentist.

For patients having coexisting gingivitis and periodontitis, see WARNINGS AND PRECAUTIONS.

Pediatrics (< 18 years of age):

No clinical data are available regarding the use of ORO CLEAR in children and adolescents younger than 18 years of age (see WARNINGS AND PRECAUTIONS).

Geriatrics (≥ 65 years of age):

Clinical studies of ORO CLEAR did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients. In general, caution should be exercised when administering ORO CLEAR in elderly patients, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy (see WARNINGS AND PRECAUTIONS).

CONTRAINDICATIONS

ORO CLEAR(0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) should not be used by the persons who are known to be hypersensitive to Chlorhexidine Gluconate, Chlorhexidine compounds or other ingredients.

WARNINGS AND PRECAUTIONS

General

- 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard can cause staining to tooth surfaces, restorations, and the dorsum of the tongue in some patients especially with prolonged use and in patients who have heavier accumulations of plaque. Staining does not affect the health or oral tissues, and can be removed from most tooth surfaces by professional dental prophylaxis. Discretion should be used in prescribing 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard for patients who have exposed root surfaces or anterior facial restorations with rough surfaces or margins, as stains on this area may be difficult to remove and may require restoration replacement in rare instances. If natural stains cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from treatment if the risk of permanent discoloration is unacceptable.
- Use of a 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard may cause an alteration in taste perception in some patients.
- Parotitis and inflammation of the salivary glands have been reported in some patients using Chlorhexidine Gluconate oral rinses (see ADVERSE REACTIONS).
- There is potential for sensitization to the active ingredient Chlorhexidine Gluconate.
- For patients having coexisting gingivitis and periodontitis, the absence of gingival inflammation following treatment with 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard may not be indicative of the absence of underlying periodontitis. Appropriate treatment of periodontitis is therefore indicated.
- For maximum effectiveness the patient should avoid rinsing their mouth, eating or drinking for about thirty minutes after using 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard.
- If the patient develops allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or diarrhea, they should seek medical attention immediately. ORO CLEAR oral rinse should not be used by persons who have a sensitivity to it or its components.

Special Populations

Pregnant Women: Use in Pregnancy:

No clinical studies with ORO CLEAR in pregnant women have not been conducted, so the benefits of using ORO CLEAR should be weighed against the possible harm to the fetus.

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. No evidence of harm to the fetus was observed in rats and rabbits at doses up to 300mg/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 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard per day.

Nursing Women:

It is not known whether Chlorhexidine Gluconate is excreted in human milk. Cautions should be exercised and the benefits of use weighed against possible risk to the infant being nursed.

In parturition and lactation studies in white rats, no evidence of impaired parturition or toxic effects to suckling pups was observed when Chlorhexidine Gluconate was administered at doses over 100 times greater than the recommended daily dose for rinsing.

Pediatrics (< 18 years of age):

The safety and efficacy of ORO CLEAR in children and adolescents younger than 18 years of age have not been established.

Geriatrics (≥ 54 years of age):

Clinical studies of ORO CLEAR did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients.

ADVERSE REACTIONS**Adverse Drug Reaction Overview**

The most common side effects occurring from the use of 0.12% Chlorhexidine Gluconate oral Rinses are staining of teeth and other oral surfaces, a slight and temporary alteration in taste perception and an increase in supra gingival calculus formation (see WARNINGS AND PRECAUTIONS). Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with the 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, keratinisation, geographic tongue, mucocele, and short frenum.

Among post marketing reports, the most frequently reported mucosal symptoms associated with 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia. Minor irritation and superficial desquamation of the oral mucosa have been seen. Parotitis and inflammation of the salivary glands have been reported in some patients using Chlorhexidine Gluconate oral rinses.

DRUG INTERACTIONS**Drug-Drug Interactions**

Interactions with other drugs have not been established.

DOSAGE AND ADMINISTRATION

Recommended Dosage

Rinse with 15 mL of solution for 30 (thirty) seconds, then expectorate. Use twice daily after breakfast and before bedtime or as prescribed. ORO CLEAR is not intended for ingestion and should be expectorated after rinsing.

Use of ORO CLEAR (0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) should begin immediately following professional dental prophylaxis. Patients should be re-examined at intervals of not more than six months and given a thorough prophylaxis. Patient referral for periodontal consultation should be done as necessary.

DO NOT SWALLOW.

Note: Wait thirty minutes after brushing with conventional toothpastes before using ORO CLEAR. Do not rinse the mouth, eat or drink for thirty minutes after using ORO CLEAR.

The suggested initial therapy is three 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.
- Discontinue use of ORO CLEAR if gingival inflammation and bleeding is controlled.
- Recall the patient in three months to assess gingival health.
- Continue use of ORO CLEAR for an additional three months if gingival inflammation and bleeding persists. 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 evaluation the severity of gingivitis.

Loe and Silness GINGIVAL INDEX (GI)

Grade	Description
1	Normal gingival, no inflammation, no coloration, no bleeding.
2	Mild inflammation, slight color 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 hemorrhage, some ulceration.

Missed Dose: If a dose of ORO CLEAR is missed, take the next dose of ORO CLEAR as scheduled. Do not double the next dose.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Center.

Ingestion of 30 to 60 ml of ORO CLEAR (0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) by a small child may result in gastric distress including nausea. Medical attention should be sought if more than 100 mL is ingested.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

ORO CLEAR (0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) provides antimicrobial activity during oral rinsing which is maintained between rinsing. The mechanism of action is time-dependent and requires a 2 step process. Firstly, the strong cationic CHG molecules attach to the anionic tooth surface and is released over the next 4-12 hours. Next, the cationic molecule attaches to the anionic surface of the bacterial cell. Prolonged contact with the bacteria eventually weakens the cell wall and disrupts its contents. Chlorhexidine is a rapidly acting agent with broad spectrum of activity. Rinsing with 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard inhibits the build-up and maturation of plaque by reducing certain microbes regarded as gingival pathogens, thereby reducing gingivitis. 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard provides antimicrobial activity during rinsing and for several hours thereafter. Microbiologic sampling of plaque has shown a general reduction of both aerobic and anaerobic bacterial counts through six months clinical use of 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard. No significant changes in bacterial sensitivity, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial flora were observed following the use of a 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard for six months. Three months after discontinued use, the number of bacteria in plaque had returned to pre-treatment levels and sensitivity or plaque bacteria to Chlorhexidine Gluconate remained unchanged.

Pharmacodynamics

One short term study and a three month clinical study examining concentration response relationships showed equal efficacy, as measured by plaque reduction, for 0.10 and 0.20% Chlorhexidine Gluconate solutions while a 0.05% solution was less effective. Studies also demonstrated that tooth and tongue discoloration increased with Chlorhexidine gluconate concentration. Also, shorter more frequent rinsing provided higher efficacy as compared to longer less frequent rinsing. A 0.12% Chlorhexidine Gluconate solution was chosen to optimize efficacy while minimizing side effects.

Pharmacokinetics

Oral Retention/De-sorption

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

Absorption:

0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard is a topical, oral rinse and should not be ingested. In the event of ingestion, studies conducted with human subjects and animals demonstrate that any ingested Chlorhexidine Gluconate is poorly absorbed in the gastrointestinal tract.

Distribution:

Approximately 30% of the Chlorhexidine present in the mouth rinse is retained in the oral cavity after rinsing. The amount retained is directly related to drug concentration (with 6.3 mg of Chlorhexidine being retained orally after a single use of a mouth rinse containing 0.12% w/v Chlorhexidine Gluconate, House Standard).

Excretion:

Excretion of Chlorhexidine Gluconate occurred primarily through the feces (approximately 90%) in 31 to 53 hours. Less than 1% of the Chlorhexidine Gluconate ingested by these subjects was excreted in the urine.

STORAGE AND STABILITY

Oro Clear (0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) must be stored between 15° and 25 ° C. Keep out of reach of children. Protect ORO-Clear from freezing.

SPECIAL HANDLING INSTRUCTIONS

No special handling instructions are available for ORO CLEAR.

DOSAGE FORMS, COMPOSITION AND PACKAGING

ORO CLEAR, Chlorhexidine Gluconate Oral Rinse 0.12% w/v House Standard is a near to neutral (pH range : 5 to 7), green coloured, spearmint flavoured liquid.

It contains the following non-medicinal ingredients : purified water, glycerine, sodium saccharin, methyl salicylate, polysorbate 80, FD&C blue #1, D&C yellow #10 and spearmint IC5-30379 and citric acid and/or sodium hydroxide to adjust the pH.

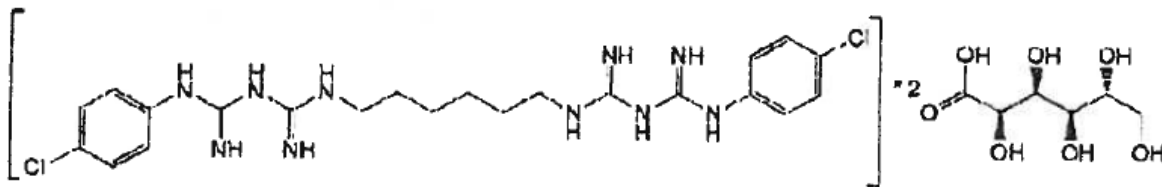
ORO CLEAR is available in 500 mL and 4 L white HDPE containers.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	Chlorhexidine Gluconate
Chemical name:	1,1-hexamethylene bis [5-4-chlorphenyle biguanide] digluconate
Molecular formula:	C₃₄H₅₄Cl₂N₁₀O₁₄ ,
Molecular mass:	897.75716 g/mol
Structural formula:	



Physiochemical Properties

Description:

Chlorhexidine Gluconate is available as Chlorhexidine Gluconate solution. It is an almost colourless to pale straw-coloured, clear or slightly opalescent liquid, that is odourless or almost odourless. It is miscible with water, with not more than five parts of ethanol (96%) and with not more than three parts of acetone. The PH of a 5% v/v solution is 5.0 to 7.0.

CLINICAL TRIALS

Human clinical trials:

A number of clinical studies have provided support for the effectiveness of 0.12% Chlorhexidine Gluconate mouth rinses in reducing plaque build-up and rate of occurrence and harshness of gingivitis as well as reducing the number of bleeding sites.

Study Location	Study Duration	Number Patients	Age	Sex	Usage Regimen	Plaque Index Scores Reduction*	Gingival Inflammation Index Scores Reduction*	Bleeding Sites Reduction*
San Antonio TX	3 months	597	18-60	M&F	According to package instruction 15 mL bid	36.1%	27.8%-45.8%	48.4%
Northfield NJ	6 months	430	18-60	M&F		60.9%	33.5%-45.4%	41.6%-52.2%
London ON	2 years	456	18-72	M&F		34.6%-56.4%	39.65%	50.3%

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

MICROBIOLOGY

In Vitro:

A non-specific mechanism of action of Chlorhexidine Gluconate gives it a wide range of antimicrobial activity against Gram-positive and Gram-negative bacteria. An in-Vitro study of the microbiocidal effect of 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard following a thirty-second exposure resulted in a 99.9% reduction in the following micro-organisms: *Aggregatibacter actinomycetemcomitans*, *Candida albicans*, *Porphyromonas gingivalis*, *Prevotella nigrescens*.

In Vivo:

To determine the efficacy of 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard in vivo, various bacteria in the microbial flora of plaque were assayed in subjects who had used either 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard or a placebo. During six months' 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard use, subjects showed reductions in total load/tooth, streptococci and actinomyces ranging from 54% to 97%. *Neisseria* and fusobacterial 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 indication that the use of 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard 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 (MIC's) for Chlorhexidine were determined on isolates of streptococci and actinomyces obtained from patients during six months 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 pretreatment values three months after product usage was discontinued. These results support that 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard usage does not result in significant changes in plaque bacterial resistance and does not cause significant changes in the plaque flora.

TOXICOLOGY

Acute Toxicity Studies:

ORO CLEAR is not classified as an acute oral toxic substance under GHS 2013 regulations.

Chronic and Sub-chronic Toxicity Studies

The only consistently observed finding in subchronic and chronic toxicity studies was the accumulation of foamy macrophages in the mesenteric lymph nodes of rats. Base on the following facts:

- 1) the macrophages did 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 and
- 4) the reaction is reversible after administration of Chlorhexidine is discontinued, it was concluded that the lesions did not represent a significant toxic effect.

Reproduction and Teratology:

No adverse reproductive or teratologic effects on rats or rabbits were observed in studies with 0.12% Chlorhexidine Gluconate mouth rinse.

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 average and in rats that ingested a 300 mg/kg dose of Chlorhexidine from their diet each day. These doses are about 140 and 1,040 times, respectively, the estimated daily ingestion from 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard with their recommended dose.

Carcinogenicity:

No evidence of carcinogenicity was observed in studies in rats in which Chlorhexidine was administered at levels up to 200 mg/kg/day for two years.

Mutagenicity:

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.

Immediate Hypersensitivity:

A variety of regimens were used in an attempt to induct and elicit immediate hypersensitivity to Chlorhexidine Gluconate in guineas pigs, rabbits, rats and man. No evidence of immediate hypersensitivity was observed in any of the tests.

Other Studies:

The emetic dose, irritation potential and sensitization potential have also been determined for 0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard. The rinse has emetic 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 oral mucosa (tested in dogs). In addition, the mouth rinse does not induce delayed contact sensitization.

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PART III: CONSUMER INFORMATION **Pr ORO CLEAR®**

Chlorhexidine Gluconate Oral Rinse, 0.12% w/v House Standard

This leaflet is part III of a three-part "Product Monograph" published when ORO CLEAR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ORO CLEAR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ORO CLEAR (0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) 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 according to the recommended dosage and frequency under supervision of a dentist.

What it does:

Chlorhexidine weakens the bacterial cell wall, disrupting cell contents, thereby killing bacteria and reducing gingivitis and the associated bleeding and inflammation of the gums.

When it should not be used:

ORO CLEAR should not be used by the persons who are known to be hypersensitive to Chlorhexidine Gluconate, Chlorhexidine compounds or other ingredients. (nonmedicinal ingredients specified below).

What the medicinal ingredient is:

Chlorhexidine Gluconate 0.12% w/v

What the important nonmedicinal ingredients are:

Purified water, glycerine, sodium saccharin, FD&C Blue #1, methyl salicylate, polysorbate 80, D&C Yellow # 10, spearmint IC5-30379.

What dosage forms it comes in:

ORO-CLEAR (0.12% w/v Chlorhexidine Gluconate Oral Rinse, House Standard) mouthwash is available in 500 mL and 4L containers.

WARNINGS AND PRECAUTIONS

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ORO CLEAR. Talk about any health conditions or problems you have.

ORO CLEAR can cause staining to tooth surfaces, restorations, and the tongue in prolonged use. This staining does not affect health and staining can be removed from most tooth surfaces by your dentist. This product may also cause a change in your taste perception which typically becomes less noticeable with continued use. Parotitis (inflammation of the parotid, one of the salivary glands) and inflammation of the salivary glands have been reported in some patients using Chlorhexidine Gluconate oral rinses. There is potential for sensitization, development of a local reaction in the mouth (e.g. irritation) to the active ingredient 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.

Use in Pregnancy: No clinical studies with Chlorhexidine Gluconate in pregnant women have been conducted. You and your doctor need to decide if this is appropriate for you.

Nursing Women: It is not known whether Chlorhexidine gluconate is excreted in human milk. You and your doctor need to discuss this issue.

Pediatrics (less than 18 years of age): The use of ORO CLEAR in pediatric patients is not recommended.

Geriatrics (greater than 65 years of age): Clinical studies of ORO CLEAR did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients. You and your doctor need to decide if this is appropriate for you.

INTERACTIONS WITH THIS MEDICATION

There are no known interactions with ORO CLEAR and other substances. Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

PROPER USE OF THIS MEDICATION

ORO CLEAR is to be administered under the supervision of a dentist.

Usual Adult Dose: Rinse with 15 mL ORO CLEAR for 30 seconds, then spit it out. Use twice daily: after breakfast and before bedtime, or as prescribed by the doctor. Do not swallow. Avoid rinsing the mouth, eating, or drinking for at least 30 minutes after using ORO CLEAR.

Overdose:

In case of accidental oral ingestion (more than 100 mL), contact your doctor or local poison control center.

If you think you have taken too much ORO CLEAR, contact your healthcare professional, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms.

Missed dose:

If a dose of ORO CLEAR is missed, take it as soon as you remember. If it is almost time for the next dose, wait until time, take the dose and resume the normal dosing schedule. Do not double the next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common side effects include staining of teeth, mouth, or tongue, change in taste perception, mouth irritation, and shedding of mouth cells. Other side effects include local irritation. If these side effects become bothersome, contact your doctor.

Serious Side Effects, How Often They Happen and What To Do About Them:

Symptom / Effect	Talk to your healthcare professional:		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Common			
Parotitis (inflammation of the parotid gland, one of the salivary glands)		✓	
Rare			
Serious allergic reaction: symptoms such as swelling of the mouth, lips, throat, difficulty in breathing, rapid heartbeat, light headedness, skin rash, itching, upset stomach or diarrhea.			✓

This is not a complete list of side effects. For any unexpected effects while using ORO-CLEAR, contact your doctor or pharmacist. Please also see Warnings and Precautions.

HOW TO STORE IT

ORO CLEAR must be stored between 15° and 25° C. Protect from freezing. Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>)

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

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting Germiphene Corporation at: 1-800-265-9931.

Germiphene Corporation, Brantford Canada

Local: 519-759-7100 Fax: 519-759-1625

Toll Free: 1-800-265-9931

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