PRODUCT MONOGRAPH
PeriDEX® ORAL RINSE
Chlorhexidine Gluconate 0.12% Antigingivitis Oral Rinse

**ACTIONS, CLINICAL PHARMACOLOGY:**
PeriDEX (0.12% chlorhexidine gluconate) is a 0.12% solution of chlorhexidine gluconate on PeriDEX provides antimicrobial activity during oral rinsing which is mediated by several processes. Microbiological sampling of plaque has shown a general reduction of bacterial species, in particular 11 bacterial species, by 48% to 77% through daily use of PeriDEX. Use of PeriDEX with the toothbrush leads to a reduction of plaque and gingivitis by reducing certain microorganisms regarded as gingival pathogens, thereby reducing gingivitis. A 0.12% solution provides antimicrobial activity during rinsing and for several hours thereafter.

There are no significant changes in bacterial sensitivity, overgrowth of potentially opportunistic organisms or any adverse changes to the oral microbial flora when PeriDEX is used for three months. These results were consistent with changes observed in plaque and gingivitis levels and severity of plaque-related bacterial communities which remained unchanged.

**INDICATIONS AND CLINICAL USE:**
PeriDEX is used as a part of a professional program for the treatment of minor to moderate gingivitis, and for management of associated gingival inflammation and accumulation of plaque in patients with normal to abnormal oral hygiene and who are non-compliant with professional prophylaxis and periodontal care.

**CONTRAINdications:**
PeriDEX (0.12% chlorhexidine gluconate) should not be used by persons who are known to be hypersensitive to chlorhexidine or any of its components. Patients who are known to have any conditions may be at increased risk.

**USE IN PREGNANCY:**
Reproductive and fertility studies with chlorhexidine gluconate have been conducted. No evidence of impaired fertility, or adverse effect on fertility in male or female reproductive parameters were observed in studies of rats and monkeys. The studies were at clinical exposure levels (20X human exposure) or at therapeutic levels (2X human exposure). There were no adverse changes in male or female reproductive parameters in studies of rats and monkeys. In contrast, in a 6-month study using 10X human exposure, no adverse changes in reproduction or fertility were observed. Studies in female rats and monkeys have indicated no evidence of tumor formation at levels of 20X human exposure.

**USE IN CHILDREN:**
Since there is no efficacy of PeriDEX in children has not been fully established, the benefits of use should be weighed against the possible risks.

**PRECAUTIONS:**

1. **For patients having existing gingival and periodontal problems, the absence of gingival inflammation following treatment with PeriDEX (0.12% chlorhexidine gluconate) may not be due to continued gingival prophylaxis, but to the continued presence of subgingival plaque.”

2. **PeriDEX is indicated for the relief of e.g. soft plaques and supracrestal on the then.

3. **A few patients may experience an unpleasant taste or bitter aftertaste. Use of PeriDEX should be terminated if this occurs.

4. **For maximum effectiveness the patient should avoid rinsing his mouth (other than brushing) and eating or drinking for about 30 minutes after using PeriDEX.

**ADVERSE REACTIONS:**

No adverse reactions of clinical significance have been observed after the use of PeriDEX (0.12% chlorhexidine gluconate) in a double-blind controlled clinical trial. In the long-term use, no changes in the oral microbial flora have been observed. Use of PeriDEX has been shown to be well tolerated in long-term use and in a variety of patients. However, minor effects may be seen in some patients.

**SYMPTOMS AND TREATMENT OF OVERDOSE:**

Ingestion of over 120 mL of PeriDEX may result in dizziness, slurred speech, and disturbances in the concentration. Treatment is symptomatic and supportive. In case of ingestion, the patient should be observed closely for at least 6 hours after the ingestion.

**DOSE AND ADMINISTRATION:**

The recommended dose is 15 mL, which should be used at least 3 times daily. Patients should be instructed to use a calibrated container to measure the correct amount of PeriDEX. Patients should rinse their mouth thoroughly with water after rinsing with PeriDEX to rinse out any remaining PeriDEX. The rinsing should continue for 30 seconds, including brushing and flossing of the teeth and gums. The mouth should then be thoroughly rinsed with water to remove all remaining PeriDEX. The patient should refrain from eating or drinking for about 30 minutes after using PeriDEX.

**INFORMATION FOR THE CONSUMER:**

This section provides information for the consumer about the use of PeriDEX. It is important to read this information before using PeriDEX.

**INCOMPATIBILITIES:**

If not taken off and rinsed out in excess hours. In laboratories and production facilities, with specially designated areas, will result in the accumulation of antigingivitis and antimicrobial action. On the other hand, the severity of gingival inflammation and accumulation of plaque in patients with normal and abnormal oral hygiene and who are non-compliant with professional prophylaxis and periodontal care.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.

**PHARMACEUTICAL INFORMATION**

**DRUG SUBSTANCE:**

Chlorhexidine gluconate 0.12% solution.