

## GINGIVAL

## Mouth Wash

### Composition

Each ml contains Chlorhexidine gluconate 0.2% w/v.

### Action

Chlorhexidine provides microbicidal activity during oral rinsing. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% over a 6-month period of Chlorhexidine use.

Approximately 30% of the drug is retained in the oral cavity following rinsing and is then released gradually into the oral fluids. Any ingested Chlorhexidine is poorly absorbed from the gastrointestinal tract.

The mean plasma level reached a peak of 0.206 mcg/gram 30 minutes after ingestion of 300 mg Chlorhexidine. The drug was not detectable in the plasma 12 hours after administration. Excretion occurred primarily through the faeces.

### Indications

Gingival is indicated for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing.

### Contraindications

Contraindicated in persons who are known to be hypersensitive to Chlorhexidine gluconate.

### Warnings

The effect of Chlorhexidine gluconate on periodontitis has not been determined. An increase in supragingival calculus has been noted in clinical testing in Chlorhexidine users.

It is unknown if use results in an increase in subgingival calculus. Calculus deposits should be removed by dental prophylaxis at intervals no greater than 6 months. Rare hypersensitivity and generalized allergic reactions have been reported.

### Pregnancy

*Category B*

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

### 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 a nursing woman uses Gingival.

### Paediatric Use

Clinical effectiveness and safety of Gingival have not been established in children less than 18 years of age.

### Adverse Reactions

The most common side effects associated with Chlorhexidine gluconate oral rinses are an increase in staining of teeth and other oral surfaces, an increase in calculus formation and alterations in taste perception.

Minor irritation and superficial desquamation of the oral mucosa, particularly in children, have been reported. Transient parotitis may occur.

### Precautions

In patients with coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with Gingival should not be used as a major indicator of underlying periodontitis.

Staining of oral surfaces, such as tooth surfaces, restorations and the dorsum of the tongue may occur. Stain is more pronounced in patients who have heavier accumulations of unresolved plaque.

Stain resulting from use of Gingival does not adversely affect health of the gingivae or other oral tissues, and can be removed from most tooth surfaces using conventional professional prophylactic techniques.

Use discretion when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by dental prophylaxis, exclude patients from treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove and may, in rare cases, necessitate replacement of restorations.

Taste perception alteration may occur while undergoing treatment. Most patients accommodate to this effect with continued use of this drug. Permanent taste alteration has not been reported.

### **Dosage and Administration**

Therapy is initiated directly following dental prophylaxis.

The patient should be instructed to rinse the mouth thoroughly for 30 seconds with the solution twice daily, morning and evening, after brushing the teeth.

The usual dose is 10 ml of undiluted solution. The solution is not intended for ingestion, and should be expectorated after rinsing.

### **Over Dosage**

The accidental ingestion of 30-60 ml by a small child (approximately 10 kg body weight) may result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if a small child ingests a large volume (120 ml or more) or if signs of alcohol intoxication develop.

### **Presentation**

Bottle of 150 ml.