INTRODUCING ALCOHOL FREE

Alcohol-Free oral rinse with proven efficacy.

• Contains 0% alcohol.
• Proven effective for treating moderate to severe gingivitis.

For more information or to order call 1-800-265-8353
Periodontal care should be referred for periodontal consultation as necessary. Recommended use is twice-daily oral rinsing for 10 seconds, morning and evening after toothbrushing.

Usual dosage is 15 mL (marked in dosage cup) of undiluted GUM Paroex. GUM Paroex is not intended for ingestion and should be expected afterward rinsing.

Rinsing the mouth (with or without mouthwashes), brushing teeth, or eating and drinking should be avoided for at least 30 minutes after using GUM Paroex. 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 GUM Paroex therapy and recall the patient in three months to assess gingival health.
- If gingival inflammation and bleeding persist, continue GUM Paroex therapy for an additional 3 months and schedule a three-month recall for evaluation.

For evidence of effective epithilization, desquamation and pain reduction. The following generally accepted grading scheme may be used in evaluating the severity of gingivitis.

Gingival Index (GI)

<table>
<thead>
<tr>
<th>Grade Description</th>
<th>1 Normal gingiva, no inflammation, no discoloration, no bleeding</th>
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<tbody>
<tr>
<td>2 Mild inflammation, slight color change, mild alteration of gingival surface, no bleeding</td>
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</tr>
<tr>
<td>3 Moderate inflammation, erythema, swelling, bleeding on probing or pressure applied</td>
<td></td>
</tr>
<tr>
<td>4 Severe inflammation, severe erythema and swelling, tendency toward spontaneous hemorrhage, some ulcération</td>
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</table>

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

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 0.1% and 0.2% chlorhexidine-glucuronate solutions while a 0.05% chlorhexidine-gluconate solution was less effective. In a three month study, anti-gingivitis efficacy was equal 0.12% and 0.2% chlorhexidine-gluconate mouth rinses. However, tooth and tongue discoloration increases with chlorhexidine concentration in both studies. Therefore, the chlorhexidine-gluconate concentration 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 discoloration was examined in another 88 day study. The data demonstrated that shorter, more frequent rinsing (i.e., 2 x 30 sec) provided optimal efficacy as compared to longer, less frequent rinsing (i.e., 1 x 60 sec).

Pharmacokinetics

Approximately 10% 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 0.12% and 0.06% chlorhexidine-glucuronate, respectively. The release rate of chlorhexidine from oral surfaces is very similar for both treatments. Based on morning/evening rinses, previous exposure to a chlorhexidine–containing mouth rinse was not observed to have any effect on subsequent reemission of chlorhexidine.

Ingestion/Excretion

GUM Paroex (0.12% chlorhexidine-glucuronate) 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 radiomarker indicated that chlorhexidine glucuronate is poorly absorbed from the gastrointestinal tract. This is in agreement with the findings from animal studies. Among five normal male volunteers, GUM Paroex was not intended for ingestion and should be expected afterward rinsing. Rinsing the mouth (with or without mouthwashes), brushing teeth, or eating and drinking should be avoided for at least 30 minutes after using GUM Paroex. 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 GUM Paroex therapy and recall the patient in three months to assess gingival health.
- If gingival inflammation and bleeding persist, continue GUM Paroex therapy for an additional 3 months and schedule a three-month recall for evaluation.

The release of chlorhexidine from oral surfaces is very similar for both treatments. Based on morning/evening rinses, previous exposure to a chlorhexidine–containing mouth rinse was not observed to have any effect on subsequent reemission of chlorhexidine.

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Safety Information

/client/Safety-Summary.pdf

CONSUMER LABEL

WARNINGS/ PRECAUTIONS

GUM Paroex (0.12% chlorhexidine-glucuronate) 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 existing gingivitis and periodontitis, see Supplemental Product Information, Precautions.

CONTRAINdications

Patients known to be hypersensitive to this drug or any of its ingredients.

CONTRAINDICATIONS

Patients known to be hypersensitive to this drug or any of its ingredients.

SPECIAL POPULATIONS

None.

USE IN CHILDREN:

The use of GUM Paroex (0.12% chlorhexidine gluconate) should not be used by children under the age of 12 years. This drug should be used only under the strict supervision of a dentist or physician.

SYMPTOMS AND TREATMENT OF OVERDOSAGE:

No unique systemic reactions associated with use of 0.12% chlorhexidine gluconate were observed. In a multi-centre study, no adverse reactions were associated with use of chlorhexidine gluconate mouth rinses.

GUM Paroex (0.12% chlorhexidine gluconate) solution is not intended for ingestion. Therefore, ingestion is not expected to be a clinical problem. In the event that ingestion should occur, it is expected to be of no clinical significance.

The product monograph is available from Sunstar Americas, Inc.

Manufactured by:

Sunstar Americas, Inc.

515 Governors Road

N1K 1C7

Sunstar

Guelph, Ontario

N1G 2T7

Sunstar

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