

**ACTISITE® (tetracycline hydrochloride) Periodontal Fiber**  
**Brief Summary of Prescribing Information**

**INDICATIONS AND USAGE**

Actisite (tetracycline hydrochloride) periodontal fiber is indicated as an adjunct to scaling and root planing for reduction of pocket depth and bleeding on probing in patients with adult periodontitis.

Treatment with Actisite is a component of an intervention program which includes good oral hygiene and scaling and root planing.

Effectiveness of repeated fiber applications in a site has not been studied.

The effects of Actisite on bone loss, tooth mobility, or tooth loss from periodontal disease has not been established.

**CONTRAINDICATIONS**

Actisite® fiber should not be used in patients who are hypersensitive to any tetracycline.

**WARNINGS**

The use of the tetracycline class during tooth development (last half of pregnancy, infancy and childhood to age of 8 years) may cause permanent discoloration of the teeth. Tetracycline drugs should not be used in this age group unless other treatment is not likely to be effective or if alternative therapy is contraindicated.

Tetracyclines as a class are associated with photosensitivity. Treatment should be discontinued at the first sign of cutaneous erythema.

Accumulations of tetracycline associated with renal failure can lead to liver toxicity. These effects have not been studied in the plasma concentration range associated with Actisite.

**PRECAUTIONS**

**General:** Actisite fibers must be removed after 10 days. Packing fibers tightly into a draining abscess without allowance for drainage might result in the formation of a lateral fistula. Fibers should not be used in an acutely abscessed periodontal pocket. Their use in chronic abscesses has not been evaluated.

As with other antibiotic preparations, Actisite (tetracycline hydrochloride) periodontal fiber therapy may result in overgrowth of nonsusceptible organisms, including fungi. Actisite should be used with caution in patients with a history of or predisposition to oral candidiasis.

The safety and effectiveness of Actisite fiber have not been established for the treatment of periodontitis in patients with coexistent oral candidiasis.

Use of antibiotic preparations may result in the development of resistant bacteria. Resistance has not been observed during 10 days of Actisite fiber therapy. The effects of prolonged treatment have not been studied.

Management of patients with periodontal disease should include a consideration of potentially contributing medical disorders.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Animal studies with Actisite fiber have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

**Pregnancy Category C:** Administration of tetracycline during pregnancy may cause permanent discoloration of teeth of offspring. Animal studies indicate that tetracyclines can cause retardation of fetal skeletal development. Actisite fiber should be administered to a pregnant woman only if clearly needed. Animal reproduction studies have not been conducted with Actisite fiber. It is also not known whether Actisite fiber can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

**Nursing Mothers**

Tetracycline appears in breast milk following oral administration. It is not known whether tetracycline is excreted in human milk following use of Actisite® (tetracycline hydrochloride) periodontal fiber. Because of the potential for serious adverse reactions from tetracycline HCl in nursing infants, Actisite fiber should be used in a nursing woman only if clearly needed.

**Pediatrics**

The safety and effectiveness of Actisite fiber in children have not been established. Oral doses of tetracycline in children up to 8 years of age have caused permanent discoloration of teeth.

**ADVERSE REACTIONS**

Actisite fiber has been studied in 1437 patients in pivotal, controlled, and open-label studies. The most frequently reported adverse reactions in the 226 patients in the pivotal clinical trials were discomfort on fiber placement (10%) and local erythema following removal (11%).

In controlled and open-label trials patients, the following adverse reactions have been reported in less than 1% of patients: oral candidiasis, glossitis, possible allergic response, staining of the tongue, severe gingival inflammation, throbbing pain, pain following placement in an abscessed area, and minor throat irritation.

**DOSAGE AND ADMINISTRATION**

Actisite (tetracycline hydrochloride) periodontal fiber for 10 days is indicated as an adjunct to scaling and root planing. Repeated fiber applications have not been studied. Actisite fiber should be inserted into the periodontal pocket until the pocket is filled. The length of fiber used will vary with pocket depth and contour. The fiber should be placed to closely approximate the pocket anatomy and should be in contact with the base of the pocket. An appropriate cyanoacrylate adhesive should be used to help secure the fiber in the pocket.

When placed within a periodontal pocket, Actisite fiber provides continuous release of tetracycline for 10 days. At the end of 10 days of treatment, all fibers must be removed. Fibers lost before 7 days should be replaced.

**HOW SUPPLIED**

Actisite® (tetracycline hydrochloride) periodontal fiber is available in boxes of 10 fibers. Each individually packaged, yellow fiber is 23 cm (9 inches) long and contains 12.7 mg of tetracycline hydrochloride.

**NDC 17314-4800-1.**

Store at controlled room temperature 15°-30°C (59°-86°F).

**Caution:** Federal law prohibits dispensing without prescription.

For product information call: 1-800-ACTISITE. To place an order call: 1-800-543-2577.

Manufactured by ALZA Corporation, Palo Alto, CA 94304 USA for:



© Procter & Gamble and ALZA Corporation, 3/94  
All rights reserved



**BETTER CONTROL OF PROBLEM SITES.**

material that interferes with the occlusion should be removed. With the RPD in place, the impression for the maxillary denture relines then can be held in place by having the patient occlude.

**Peter J. Pappas, D.M.D.**  
**Lander, Wyo.**

**Author's response:** I appreciated hearing Dr. Pappas' views, which are valid. The goals he mentioned are achieved by many techniques, among them the one I described in the April JADA article. We both agree that impression material should not be allowed to accumulate between the framework and the prepared rests. The technique I described requires that the RPD be seated rapidly after placing the Permadyne; moderate occlusal force is placed on it by hand to seat it into the rests and indirect retainers; and the patient closes into occlusion to hold it in place while the impression sets. I fully assume that the RPD frame fits adequately pre-reline, and I do not frequently see reasons to trim the denture after relining or rebasing the RPD. Often, the reverse is true, because the teeth have worn during previous service.

I thank Dr. Pappas for his comments and for sharing his technique with us.

**Gordon J. Christensen,**  
**D.D.S., Ph.D.**  
**Provo, Utah**