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1: Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 1997 Feb;83(2):222-30.

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5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: I. Clinical demonstration of acceleration of healing and resolution of pain.

[Khandwala A](#), [Van Inwegen RG](#), [Alfano MC](#).

Shaman Pharmaceuticals, Inc., South San Francisco, Calif., USA.

5% Amlexanox oral paste (Aphthasol) was studied in four vehicle-controlled, randomized, double-blind, parallel group, multicenter, clinical studies involving 1335 subjects who had 1 to 3 aphthous ulcers less than 48 hours old at enrollment. Subjects applied study pastes directly to ulcers four times a day until ulcers healed or for the duration of the study, whichever occurred first. Ulcer size was measured by the investigator and pain was evaluated by the subject; the primary determinant of efficacy was the percentage of subjects with complete healing of ulcers and complete resolution of ulcer pain. The vehicle had marginal beneficial effects as would be expected from a covering material, but statistical significance over no treatment was inconsistent. However, these studies, both individually and collectively, clearly demonstrated in a highly significant and consistent manner that in comparison to both Vehicle and No Treatment 5% Amlexanox oral paste accelerates the resolution of pain and healing of aphthous ulcers.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 9117754 [PubMed - indexed for MEDLINE]

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