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1: Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 1997 Feb;83(2):231-8.

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## 5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: II. Pharmacokinetics and demonstration of clinical safety.

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

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

The safety of 5% Amlexanox paste was demonstrated in the following clinical studies: vehicle-controlled safety and efficacy studies; dermal irritation and sensitization studies; single and multiple dose pharmacokinetic studies; and a 28-day in use safety study. Minimal adverse experiences were observed with the 991 subjects that were exposed to 5% Amlexanox paste. No significant irritation or sensitization was associated with 5% Amlexanox paste. Pharmacokinetic studies indicated that systemic levels of Amlexanox are most likely due to normal gastrointestinal absorption with only limited absorption directly through the ulcer. After a 100 mg dose of 5% Amlexanox paste the average maximum concentration of Amlexanox in the serum was 120 ng/ml, occurring 2.4 hours after application. The half-life for elimination of Amlexanox was 3.5 hours, and there was no evidence of accumulation with multiple applications. Overall, the data indicate that 5% Amlexanox paste (Aphthasol) is safe for the treatment of recurrent minor aphthous ulcers.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 9117755 [PubMed - indexed for MEDLINE]

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