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1: J Oral Maxillofac Surg. 1993 Mar;51(3):243-8; discussion 248-9.

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A double-blind study of topically applied 5% amlexanox in the treatment of aphthous ulcers.

[Greer RO Jr](#), [Lindenmuth JE](#), [Juarez T](#), [Khandwala A](#).

Division of Oral Pathology and Oncology, University of Colorado Health Sciences Center, School of Dentistry, Denver.

A double-blind trial of amlexanox (C₁₆H₁₄N₂O₄) was carried out in 32 patients with recurrent oral aphthous ulcerations. During the treatment period, which lasted for 3 days, patients received either placebo topical paste or 5% amlexanox paste. The paste was applied by the investigator twice per day for 3 days and once on the fourth day. Efficacy was assessed by the following parameters: 1) pain measured by the patients marking a 15-cm line between poles connoting no pain versus severe pain; 2) erythema evaluated by the investigator on a four-point scale ranging from none to strong; 3) size determined by investigator measurement of the perpendicular dimensions of the ulcer; and 4) an investigator's improvement scale consisting of six rank-ordered points from -1 for worsening of the ulcer with respect to previously described criteria to +4 when the ulcer had healed completely. All evaluations were based on a comparison with the day 1 visit of the patient. Outcomes for patients receiving the active ingredient were superior on all four criteria of effectiveness. Group differences for all criteria but pain reduction were statistically significant ($P < .05$). No side effects were reported. It was concluded that amlexanox is effective in reducing aphthous ulcer erythema, pain, and lesional size.

Publication Types:

- Clinical Trial
- Multicenter Study
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PMID: 8445464 [PubMed - indexed for MEDLINE]

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