

Sublingual Epinephrine Film's Mucoadhesive Properties Ensures Consistent Oral Placement and Drug Release

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Introduction: Epinephrine is the first-line treatment for severe allergic reactions, including anaphylaxis. Prompt and reliable action are critical for patient outcomes. Recent advancements have led to the development of DESF, a sublingual film containing a novel epinephrine prodrug.

Methods: AQ109301, a randomized, cross-over trial in healthy adults evaluated the pharmacokinetics (PK) and pharmacodynamics (PD) of epinephrine delivered via sublingual film (DESF) compared to epinephrine autoinjectors (EAI) and manual IM injection (IM). Intraoral film placement and movement were evaluated to assess any impact on variability in PK and PD.

Results: DESF delivery resulted in epinephrine PK comparable to EAI or IM injection. DESF PK and PD remained consistent independent of small variations in film location. Analysis of residual film location between 1.5 to 3 minutes post-administration revealed minimal displacement, with 87.5% of subjects having no change in film location between timepoints. When movement was noted, there were no significant differences between subjects with or without film movement for geometric mean C_{max} (351.2 and 489.4 pg/mL, respectively; $p = 0.52$) or median T_{max} (12 and 12 minutes, respectively, $p = 0.99$). Similarly, there were no significant differences in median change in systolic blood pressure between subjects with or without film movement (27.33 and 23.00 mmHg, respectively; $p = 0.46$).

Conclusion: The initial placement or subsequent movement of the sublingual film had no impact on epinephrine pharmacokinetics or pharmacodynamics, with all results comparable to injection. These findings suggest that sublingual epinephrine film offers a consistent, robust and permissive method of drug delivery in anaphylaxis management.