Pharmacokinetics of a Novel Amphetamine Extended-Release Orally Disintegrating Tablet in Children with Attention-Deficit/Hyperactivity Disorder


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ABSTRACT

Background:
A novel formulation for treating attention-deficit/hyperactivity disorder (ADHD) has recently been developed—amphetamine extended-release orally disintegrating tablets (AMP XR-ODTs). In this study, we assessed the rate of absorption and exposure of AMP XR-ODT under fasted conditions in children with ADHD.

Methods:
Children (6–12 years) with ADHD were enrolled in a single-dose, open-label, single-period pharmacokinetic (PK) study. Patients were stratified by age (6–7, 8–9, and 10–12 year olds) and were dosed with 18.8-mg AMP XR-ODT under fasted conditions. Plasma samples were analyzed for d- and l-amphetamine. Maximum plasma concentration (Cmax), time to maximum plasma concentration (Tmax), area under the concentration-time curve from time zero–infinity (AUCinf), weight-normalized clearance (CL/F), and weight-normalized volume of distribution (Vz/F) were assessed. The geometric mean and 95% confidence intervals (CIs) were calculated for weight-normalized CL/F and Vz/F in each age group to determine if the 95% CIs were within the target range of 60%–140%.

Results:
A total of 28 children completed the study. The 95% CIs for the geometric mean CL/F/kg and Vz/F/kg for both d- and l-amphetamine fell within the target range of 60%–140% for each age group, thus meeting the primary end point. Four participants experienced treatment-related adverse events, including vomiting (n = 3), abdominal pain (n = 2), dry mouth (n = 1), and insomnia (n = 1).

Conclusions:
AMP XR-ODT, a novel formulation that does not require swallowing an intact tablet or capsule, was well tolerated and demonstrated a PK profile consistent with once-daily dosing in children with ADHD.