Effect of Food Intake on the Pharmacokinetics of a Novel Methylphenidate Extended-Release Oral Suspension for Attention Deficit Hyperactivity Disorder.

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Abstract

We conducted an open-label, single-dose, randomized, crossover study in healthy adults to assess the impact of food on the bioavailability of 60 mg methylphenidate extended-release oral suspension (MEROS; Quillivant XRTM)-a long-acting stimulant for the treatment of attention deficit hyperactivity disorder by comparing the pharmacokinetic parameters under fed and fasting conditions. When MEROS 60 mg was administered under fed conditions compared to fasting conditions, the exposure of methylphenidate (d enantiomer) was higher, with a mean area under the plasma concentration-vs-time curve (AUC)0-t of 160.2 ng·h/mL vs 140.4 ng·h/mL, and a mean AUC0-inf of 163.2 ng·h/mL vs 143.7 ng·h/mL, respectively. The ratios of the ln-transformed geometric means for methylphenidate for AUC0-t and AUC0-inf were 119.5% (90%CI, 115.7% to 123.5%) and 119.0% (90%CI, 115.2% to 122.8%), respectively, within the standard 80% to 125% bioequivalence acceptance range indicating no food effect on the overall exposure (rate and extent). There was a small increase in the peak plasma concentration (127.6% [90%CI, 119.9% to 135.8%]). However, this effect was small and not likely to be clinically significant. Overall, MEROS 60 mg was safe in both the fed and fasting condition when administered to healthy volunteers in this study.