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Extended-Release Methylphenidate (Ritalin® LA[1])

A Viewpoint by Sharon B. Wigal

Department of Paediatrics, University of California, Irvine, California, USA

Extended-release methylphenidate (Ritalin® LA) has recently been approved in the USA for the treatment of attention deficit/hyperactivity disorder (ADHD) in children aged 6 years or older. This orally administered formulation obviates the need for midday dosing and the difficulties that ensue in a school setting arising from that need. The use of a spheroidal oral drug absorption system (SODAS™) allows for the bimodal release of immediate- and delayed-release beads. The dosage ranges between 20 and 60 mg/day and is increased in 10mg increments.

This extended-release formulation of methylphenidate has a significant effect (i.e. less impairment) compared with placebo on both behavioral and cognitive measures, which are sensitive to time-course effects of stimulant treatment. Significant improvements were shown in both the deportment and attention factor components of the Swanson, Kotkin, Angler, M-Flynn and Pelham (SKAMP) rating scale, and also in productivity on mathematical problems. Extended-release methylphenidate is rapidly absorbed, with a bioavailability in children and adults similar to that of the same total dose of immediate-release methylphenidate given as two doses 4 hours apart. Peak plasma concentrations vary substantially between individual participants, particularly in children. In 6- to 12-year-old children diagnosed with ADHD, this single-dose product was shown to significantly improve symptoms in both the predominantly hyperactive/impulsive subtype and combined inattentive and hyperactive/impulsive subtype of ADHD compared with placebo.

Similar to other methylphenidate products, 78 to 97% of the dose is eliminated in the urine in the form of metabolites with ritalinic acid being the primary metabolite. Dose administration following a high-fat diet, compared with a fasting condition, in healthy adults delayed drug absorption. The long-term effects of extended-release methylphenidate are not known at this time. The pharmacokinetics of this formulation has not been studied yet in preschool-aged children (<6 years of age). Overall, extended-release methylphenidate is well tolerated, with the most frequent adverse events reported in children being headache, insomnia and abdominal pain. ▲