A non-interventional study of extended-release methylphenidate in the routine treatment of adolescents with ADHD: effectiveness, safety and adherence to treatment.

Sobanski E, Döpfner M, Ose C, Fischer R.

Department of Psychiatry and Psychotherapy, Central Institute of Mental Health, Medical Faculty Mannheim, University of Heidelberg, J 5, 69159, Mannheim, Germany, esther.sobanski@zi-mannheim.de.

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This multi-centre, open-label, non-interventional study evaluates effectiveness, safety and adherence to treatment of a specific extended-release methylphenidate with a 50 % immediate and a 50 % extended-release component (Medikinet® retard) in the clinical routine treatment of 381 adolescents with ADHD and a mean age of 14.0 ± 1.9 years. ADHD and associated psychiatric symptoms, medication status and dosage frequency, treatment adherence and adverse events were assessed at baseline and after a median treatment length with Medikinet® retard of 70 days. Primary outcome criterion was the change of ADHD symptom severity from baseline to endpoint according to the ADHD-KGE (German: ADHS-Klinische Gesamteinschätzung) change score. At baseline, 4.2 % of the patients were treatment naïve, 92.7 % had previously received different methylphenidate formulations and 3.1 % had received atomoxetine or amphetamine. During the study, patients received a mean daily dose of 35.7 ± 15.1 mg Medikinet® retard. At endpoint, in 78 % of patients, the total ADHD symptom severity was reduced, in 20.4 %, it remained unchanged and in 1.6 %, it was worsened. The mean ADHD-KGE total ADHD symptom score was reduced from 1.8 ± 0.7 (moderate) at baseline to 0.8 ± 0.5 (mild; $p < 0.001$) at endpoint; the mean ADHD-KGE total-associated symptom score was reduced from 1.9 ± 0.7 (moderate) at baseline to 1.0 ± 0.6 (mild; $p < 0.0001$) at endpoint. After the medication switch from previous methylphenidate formulation to Medikinet® retard, multiple dosing with ≥3 daily medication intakes was reduced from 12.9 % at baseline to 3.1 % at endpoint ($p < 0.001$). Adherence to treatment was improved in 37 % of patients. Most frequent adverse events were loss of appetite and gastrointestinal problems. The findings suggest that pharmacologically treated adolescents with ADHD and insufficient

symptom reduction and/or treatment adherence benefit from switching to Medikinet® retard and that it is well tolerated when given in clinical routine care.