



# EDCO FORUM<sup>®</sup>

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## STIMULANT THERAPY IS EFFECTIVE FOR ONCE-A-DAY TREATMENT OF CHILDREN WITH ADHD

**C**ONCERTA<sup>®</sup> (methylphenidate HCL) Extended-release Tablets, a central nervous system (CNS) stimulant, are distributed and marketed by **McNeil Consumer & Specialty Pharmaceuticals** (Fort Washington, PA). CONCERTA Tablets are indicated for the treatment of attention deficit hyperactivity disorder (ADHD). CONCERTA is an integral part of a total treatment program for ADHD that may include psychological, educational, and social programs for patients.

According to the DSM-IV, a diagnosis of ADHD implies the presence of hyperactivity, impulsiveness, and inattentive symptoms that cause clinically significant impairment in social, academic, or occupational functioning before age seven. These symptoms are present in school (or work) and at home. The diagnosis must be based upon a complete history and evaluation of the child.

“ADHD can be present in a lot of different ways to clinicians,” says Jeffrey H. Newcorn, MD, Associate Professor of Psychiatry and Pediatrics, Mount Sinai School of Medicine (New York, NY). “Symptoms of ADHD may not be apparent during the clinical visit with the patient. It’s important to collect information from parents, teacher, and the child about the child’s level of function in different settings. ADHD doesn’t only affect behavior and academic performance in the classroom; it also affects interactions with adults and peers, participation in group activities, and ability to work independently on tasks like reading and homework.”

CONCERTA has a unique medication-release delivery system. When given once a day in the morning, it produces an ascending-pattern plasma drug level generated by the tablet’s osmotically released, timed drug-delivery system, providing symptom control for 12 hours at all strengths. Children naïve to stimulant treatment may be started directly on 18 mg CONCERTA, given once daily in the morning, and titrated up weekly as needed. This dosage is equivalent to immediate-release methylphenidate (MPH) HCl 5 mg, 3 times daily (*I*). CONCERTA tablets are supplied in four dosage strengths: 18, 27, 36, and 54 mg, each providing 22% of the total dose in the drug overcoat, with the remainder of medication being precisely delivered throughout the day. While the 18 mg dose is considered a starting dose for stimulant-naïve patients, long-term studies have shown that the majority (84%) are likely to be titrated to a more effective dose of 36-mg or 54-mg strengths.

### Clinical Studies With CONCERTA

Stimulants are more effective than atomoxetine for once-daily treatment of ADHD, according to research presented at the American Academy of Child and Adolescent Psychiatry (AACAP), October, 2003, by Kenneth W. Steinhoff, MD, Associate Clinical Professor, University of California-Irvine. Dr. Steinhoff, the lead investigator of the study, declined any pharmaceutical funding for the study. The three drugs studied were CONCERTA, mixed amphetamine salts (Adderall XR), and once-daily atomoxetine (Strattera).

The authors compared the data in large placebo-controlled studies that the different product companies had submitted to the Food and Drug Administration as their Phase III registration trials. The Likert scale changes and the effect size (magnitude of drug effect), based on baseline standard deviation, were reported. Teacher and parent evaluations were compared.

The Likert scale difference on parent evaluations was 0.76 for CONCERTA, 0.51 for mixed amphetamines, and 0.17 for atomoxetine. On the teacher evaluations, the Likert scale difference was 0.75 for CONCERTA, 0.52 for mixed amphetamines, and 0.13 for atomoxetine. "The teachers do not see the effect size that parents see," Dr. Steinhoff said. Much ADHD symptomatology is experienced at home with homework, bedtime preparations, and getting ready for school in the morning.

Another presentation at the AACAP meeting was by Stephen V. Faraone, PhD, from Massachusetts General Hospital and Harvard Medical School (Boston, MA). He indicated the impact of drug holidays in 289 children, age 6 to 13 years, who received CONCERTA individually titrated upwards or down by 18 mg for

one year. Adherence was excellent, and on average, 86% of patients adhered to their individualized once-daily dose of CONCERTA; this was 92% for patients who did not take planned drug holidays. In fact, drug holidays may adversely impact ADHD children, particularly older children, and caution is recommended. The benefits of continuous therapy should be discussed with patients, parents, or care-givers, to help ensure that they are aware of the possible lower outcomes associated with use of drug holidays.

Daniel J. Cox, PhD, *et al.* from the University of Virginia (Charlottesville, VA). presented data at the AACAP meeting that suggest between 40% and 80% of ADHD patients continue to suffer as adolescents. This first study demonstrates that once-daily CONCERTA improves on-road driving performance of adolescent males with ADHD by significantly reducing the number of driving errors arising from inattention. These effects are positively correlated with medication dosage. CONCERTA produces a smooth profile of plasma concentration over 12 hours and may facilitate a constant level of driver attention, and thus contribute to a reduction in the risk of serious road

traffic accidents for adolescent drivers with ADHD.

CONCERTA should not be given to patients who have significant anxiety, tension, or agitation, because it may make these conditions worse; also, CONCERTA should not be given to patients who have glaucoma or Tourette's syndrome. In clinical studies, the most common side effects were headache, stomach pain, sleeplessness, and decreased appetite.



For more information concerning CONCERTA, call McNeil Consumer & Specialty Pharmaceuticals at 1-888-440-7903, or visit the product Web site at [www.concerta.net](http://www.concerta.net).

## Reference:

1. Greenhill, L.L., *et al.* *J. Am. Acad. Child Adolesc. Psychiatry* 2002;41:26S-29S.