



# EDCO FORUM<sup>®</sup>

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## BETTER DRIVING PERFORMANCE OF TEENS WITH ADHD RECEIVING ONCE-A-DAY CONCERTA<sup>®</sup> MAY BE DUE TO THE DRUG'S UNIQUE DELIVERY SYSTEM

**C**ONCERTA<sup>®</sup> (methylphenidate HCl) **Extended-release Tablets (MPH)**, 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.

CONCERTA has a unique medication-release delivery system (**OROS<sup>®</sup>**). When given once a day in the morning, the medication 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 dosage strengths. Treatment may be started directly on 18 mg CONCERTA, given once daily in the morning, and titrated up weekly as needed. The 18-mg dose of CONCERTA is equivalent to immediate-release methylphenidate (MPH) HCl 5 mg, 3 times daily (1). 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. Although the 18-mg dose is considered a starting dose for stimulant-naïve patients, long-term studies have shown that the majority (84%) of patients are likely to be titrated to a more effective dose of 36-mg or 54-mg strengths.

### Driving Performance is Better in Patients Receiving CONCERTA

A recent pilot study (2) suggests that CONCERTA may help reduce the risk of accidents for adolescent drivers with ADHD throughout the day and into the evening. This was a randomized, crossover, single-blind study that compared osmotic, controlled-release oral formulation (OROS) CONCERTA (MPH), given once a day, with immediate-release MPH (Ritalin), given in equal doses three times a day. Driving performance in six male ADHD-diagnosed adolescent drivers, aged 16 to 19 years, was studied. Participants were maintained on each medication for seven days after their optimal dose was determined. On the seventh day of each medication, participants completed computer-simulated driving courses at 2:00 pm, 5:00 pm, 8:00 pm, and 11:00 pm. Impaired Driving Scores (IDS) were calculated using data from the Atari Research Driving Simulator, which were recorded eight times per second on nine measures of steering control, braking ability, and speed control. In addition, daily driving diaries regarding participants' risky driving practices and driving errors were reported, and showed fewer driving risks were taken when patients were on CONCERTA.

Results of IDS scores remained stable when patients received once-daily CONCERTA, but patients receiving MPH t.i.d. showed worsening scores in the evenings beginning at 8:00 pm. The medication's unique delivery system minimizes the ups and downs in

blood levels experienced with stimulant medications taken several times a day. In conclusion, the authors report that the participants receiving CONCERTA demonstrated significantly less variability and better driving performance, particularly in the evenings, compared with those receiving MPH t.i.d.

### **CONCERTA Improved Likert Scale Scores in a Comparative Study**

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.

Symptoms of ADHD come in two main clusters that show up in different forms at different ages, reports Jefferson Prince, MD, Director of Child Psychiatry, North Shore Medical Center (Salem, MA), and on Staff of Child Psychiatry at Massachusetts General Hospital and Harvard Medical School (Boston, MA). In a child in the third grade, observes Dr. Prince, the symptoms may come up as a history of (1) hyperactivity with wiggling, fidgeting, and being unable to sit; and (2) impulsivity with interrupting and blurting out answers, not waiting for questions to be finished. These symptoms begin early in life and interfere with

daily functioning. In referring to the Cox study (2), Dr. Prince says, "Both adolescents and adults with ADHD who are not in treatment are much more likely to have driving violations and accidents. With medication [CONCERTA]," he adds, "ADHD patients drive safer."

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; contact a McNeil representative at APA, booth #228; or visit the product Web site at [www.concerta.net](http://www.concerta.net).

### **References:**

1. Greenhill, L.L. et al. *J. Am. Acad. Child Adolesc. Psychiatry* 2002;41:26S-29S.
2. Cox, D.J. et al. *J. Am. Acad. Child Adolesc. Psychiatry* 2004;43(3):269-275.