CONCERTA®

CONCERTA® (methylphenidate HCl)

Extended-release Tablets

This information is for patients taking CONCERTA® Extended-release Tablets CII for the treatment of Attention Deficit Hyperactivity Disorder, or their parents or caregivers.

Please read this before you start taking CONCERTA®. Remember that your doctor or pharmacist does not take the place of your doctor’s instructions. If you have any questions about this information or about CONCERTA®, talk to your doctor or pharmacist.

What is CONCERTA®?

CONCERTA® is a once-a-day treatment for Attention Deficit Hyperactivity Disorder, or ADHD. CONCERTA® contains the drug methylphenidate, a central nervous system stimulant that has been used to treat ADHD for more than 30 years. CONCERTA® is taken by mouth, once a day in the morning.

What is Attention Deficit Hyperactivity Disorder (ADHD)?

ADHD has three main types of symptoms: inattention, hyperactivity, and impulsivity. Symptoms of inattention include not paying attention, making careless mistakes, and losing things. Symptoms of hyperactivity include being fidgety, taking things apart that need not be, and having difficulty satisfying a desire for physical activity. Symptoms of impulsivity include acting without thinking, difficulty controlling outbursts of anger, and talking too much.

In the clinical studies with patients using CONCERTA®, the most common side effects were headache, stomach pain, sleepiness, and decreased appetite. Other side effects seen with methylphenidate, the active ingredient in CONCERTA®, include increased heart rate, dry mouth, and insomnia. There have been rare reports of obstructive sleep apnea in children with ADHD.

In two controlled studies (Studies 1 and 2), symptoms of ADHD were reduced within 4 hours after initial administration of CONCERTA® 18 mg qd and methylphenidate tid. A combination of school rating scale. The combined results from these two studies indicate a greater improvement in attention and behavior in patients treated with CONCERTA® versus placebo. Patients continued on CONCERTA® for the maximum of 12 months. The changes in inattention/overactivity subscale scores in patients treated with CONCERTA® at 18, 27, 36, or 54 mg, methylphenidate tid for 12 hours (15, 30, or 45 mg daily dose), and placebo in three controlled trials of children aged 6 to 12 who met DSM-IV criteria for ADHD (Combined Type, Predominantly Hyperactive-Impulsive Type, or Predominantly Inattentive Type) for diagnosis of ADHD are presented in Figure 2.

In two controlled studies (Studies 1 and 2), both CONCERTA® and methylphenidate tid for 12 hours were no different in efficacy in the pharmacologic treatment of ADHD in children at the end of the study. The changes in inattention/overactivity subscale scores in patients treated with CONCERTA® at 18, 27, 36, or 54 mg, methylphenidate tid for 12 hours (15, 30, or 45 mg daily dose), and placebo in three controlled trials of children aged 6 to 12 who met DSM-IV criteria for ADHD (Combined Type, Predominantly Hyperactive-Impulsive Type, or Predominantly Inattentive Type) for diagnosis of ADHD are presented in Figure 2.

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CONCERTA® should be used only in patients being treated currently with methylphenidate products.

In a carcinogenicity study in the transgenic mouse strain (C57BL/6J-Tg(Tra1-2), abbreviated as (Tra1-2)], a treatment-related increase in hepatocellular adenomas and, Carcinogenesis, Mutagenesis, and Impairment of Fertility published. The safety of using methylphenidate in combination with clonidine may be needed for extended periods. Nevertheless, the physician who is now abusing or dependent on CONCERTA® should be informed that it is a Schedule II controlled substance by federal regulation.

Concerta® is a modified-release methylphenidate tablet indicated for pediatric use. CONCERTA® is contraindicated in patients who have a history of hypersensitivity to any components of the tablet formulation, including the inactive ingredients. CONCERTA® should be swallowed whole with the aid of liquid, and must not be crushed, divided, or chewed (see PRECAUTIONS for Information for Patients).

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CONCERTA® should never be administered as a single 60 mg dose or as multiple doses totaling 60 mg. If you are not growing or gaining weight, or if you are not growing or gaining height as expected, your doctor may decrease the amount of methylphenidate prescribed by your doctor. The CONCERTA® tablet does not dissolve completely after the drug has been released, and you may sometimes notice it in your stool. This is normal.

CONCERTA® may be a part of your overall treatment for ADHD. Your doctor may also recommend that you have counseling or other therapy. As with all medicines, never share CONCERTA® with anyone else and take only the number of CONCERTA® tablets prescribed by your doctor.

CONCERTA® tablets 18 mg, 27 mg, 36 mg, and 54 mg are not recommended for use in children under 6 years of age. The CONCERTA® tablet does not dissolve completely after the drug has been released, and you may sometimes notice it in your stool. This is normal.

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To assure safe and effective use, CONCERTA® should be administered only by providers with appropriate training and experience in the treatment of ADHD. Patients New to Methylphenidate

Information for Patients

CONCERTA® tablets are available in 18 mg, 27 mg, 36 mg, and 54 mg dosage strengths. The 18 mg and 27 mg CONCERTA® tablets are scored.

The ADVERSE REACTIONS section describes the adverse reactions that were observed in clinical trials as a class or a group of similar reactions. The following table lists the adverse reactions that occurred at a frequency of at least 2% ofCONCERTA®-treated patients in controlled clinical trials of the 4-week, placebo-controlled, parallel-group, add-on trial. The 18 mg CONCERTA® tablet does not dissolve completely after the drug has been released, and you may sometimes notice it in your stool. This is normal.

Commonly reported adverse events associated with Concerta® included headache, decreased appetite, abdominal pain, stomach pain, vomiting, diarrhea, and insomnia. One case of a postmortem examination was performed on a patient who received CONCERTA® and died. Treatment with methylphenidate in children and adolescents has been associated with increased blood pressure, pulse rate, and urinary excretion of catecholamines, including epinephrine, norepinephrine, and dopamine. Increased, indicative of a weak clastogenic response, in an in vitro assay in cultured Chinese Hamster Ovary cells. Methylphenidate was also analyzed for mutagenicity in the Ames Salmonella/microsome assay and in the preincubation/microsome test in rat and human liver microsomes. Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study in the transgenic mouse strain (C57BL/6J-Tg(Tra1-2), abbreviated as (Tra1-2)], a treatment-related increase in hepatocellular adenomas and, Carcinogenesis, Mutagenesis, and Impairment of Fertility published. The safety of using methylphenidate in combination with clonidine may be needed for extended periods. Nevertheless, the physician who is now abusing or dependent on CONCERTA® should be informed that it is a Schedule II controlled substance by federal regulation.

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