

## INFORMATION FOR PATIENTS TAKING CONCERTA™ OR THEIR PARENTS OR CAREGIVERS

### 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, this information 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 each day in the morning.

#### What is Attention Deficit Hyperactivity Disorder?

ADHD has three main types of symptoms: inattention, hyperactivity, and impulsiveness. Symptoms of inattention include not paying attention, making careless mistakes, not listening, not finishing tasks, not following directions, and being easily distracted. Symptoms of hyperactivity and impulsiveness include fidgeting, talking excessively, running around at inappropriate times, and interrupting others. Some patients have more symptoms of hyperactivity and impulsiveness while others have more symptoms of inattentiveness. Some patients have all three types of symptoms.

Many people have symptoms like these from time to time, but patients with ADHD have these symptoms more than others their age. Symptoms must be present for at least 6 months to be certain of the diagnosis.

#### How does CONCERTA™ work?

Part of the CONCERTA™ tablet dissolves right after you swallow it in the morning, giving you an initial dose of methylphenidate. The remaining drug is slowly released during the day to continue to help lessen the symptoms of ADHD. Methylphenidate, the active ingredient in CONCERTA™, helps increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

#### Who should NOT take CONCERTA™?

You should NOT take CONCERTA™ if:

- You have significant anxiety, tension, or agitation since CONCERTA™ may make these conditions worse.
- You are allergic to methylphenidate or any of the other ingredients in CONCERTA™.
- You have glaucoma, an eye disease.
- You have tics or Tourette's syndrome, or a family history of Tourette's syndrome.

Talk to your doctor if you believe any of these conditions apply to you.

#### How should I take CONCERTA™?

**Do not chew, crush, or divide the tablets.** Swallow CONCERTA™ tablets whole with the help of water or other liquids, such as milk or juice.

Take CONCERTA™ once each day in the morning.

You may take CONCERTA™ before or after you eat.

Take the dose prescribed by your doctor. Your doctor may adjust the amount of drug you take until it is right for you. From time to time, your doctor may interrupt your treatment to check your symptoms while you are not taking the drug.

#### What are the possible side effects of CONCERTA™?

In the clinical studies with patients using CONCERTA™, the most common side effects were headache, stomach pain, sleeplessness, and decreased appetite. Other side effects seen with methylphenidate, the active ingredient in CONCERTA™, include nausea, vomiting, dizziness, nervousness, tics, allergic reactions, increased blood pressure and psychosis (abnormal thinking or hallucinations).

This is not a complete list of possible side effects. Ask your doctor about other side effects. If you develop any side effect, talk to your doctor.

#### What must I discuss with my doctor before taking CONCERTA™?

Talk to your doctor **before** taking CONCERTA™ if you:

- Are being treated for depression or have symptoms of depression such as feelings of sadness, worthlessness, and hopelessness.
- Have motion tics (hard-to-control, repeated twitching of any parts of your body) or verbal tics (hard-to-control repeating of sounds or words).
- Have someone in your family with motion tics, verbal tics, or Tourette's syndrome.
- Have abnormal thoughts or visions, hear abnormal sounds, or have been diagnosed with psychosis.
- Have had seizures (convulsions, epilepsy) or abnormal EEGs (electroencephalograms).
- Have high blood pressure.
- Have a narrowing or blockage of your gastrointestinal tract (your esophagus, stomach, or small or large intestine).

Tell your doctor **immediately** if you develop any of the above conditions or symptoms while taking CONCERTA™.

#### Can I take CONCERTA™ with other medicines?

Tell your doctor about **all** medicines that you are taking. Your doctor should decide whether you can take CONCERTA™ with other medicines. These include:

Other medicines that a doctor has prescribed.

Medicines that you buy yourself without a prescription.

Any herbal remedies that you may be taking.

You should not take CONCERTA™ with monoamine oxidase (MAO) inhibitors.

While on CONCERTA™, do not start taking a new medicine or herbal remedy before checking with your doctor.

CONCERTA™ may change the way your body reacts to certain medicines. These include medicines used to treat depression, prevent seizures, or prevent blood clots (commonly called "blood thinners"). Your doctor may need to change your dose of these medicines if you are taking them with CONCERTA™.

#### Other Important Safety Information

Abuse of methylphenidate can lead to dependence.

Tell your doctor if you have ever abused or been dependent on alcohol or drugs, or if you are now abusing or dependent on alcohol or drugs.

**Before** taking CONCERTA™, tell your doctor if you are pregnant or plan on becoming pregnant. If you take methylphenidate, it may be in your breast milk. Tell your doctor if you are nursing a baby.

Tell your doctor if you have blurred vision when taking CONCERTA™.

Slower growth (weight gain and/or height) has been reported with long-term use of methylphenidate in children. Your doctor will be carefully watching your height and weight. If you are not growing or gaining weight as your doctor expects, your doctor may stop your CONCERTA™ treatment.

Call your doctor **immediately** if you take more than the amount of CONCERTA™ prescribed by your doctor.

#### What else should I know about CONCERTA™?

CONCERTA™ has not been studied in children under 6 years of age.

The CONCERTA™ tablet does not dissolve completely after all 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™ should be stored in a safe place at room temperature (between 59°-86° F). Do not store this medicine in hot, damp, or humid places.

#### Keep out of the reach of children.

For more information call 1-888-440-7903 or visit [www.concerta.net](http://www.concerta.net)

Manufactured, distributed, and marketed by ALZA Corporation, Mountain View, CA 94043.

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