

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE



**CONCERTA®**

Methylphenidate Hydrochloride Extended-release Tablets

Read this carefully before you start taking **Concerta** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Concerta**.

#### Serious Warnings and Precautions

- **Drug Dependence**

Like other stimulants, Concerta has the potential to be abused. This can lead to you becoming dependent on Concerta or feeling like you need to take more of it over time.

#### What is Concerta used for?

- Concerta is a once-a-day treatment for Attention Deficit Hyperactivity Disorder, or ADHD, in children 6 years of age or older, adolescents and adults.

**Concerta is NOT recommended for use in children under 6 years of age.**

Treatment with Concerta, or other stimulants, should be combined with other measures such as psychological counselling, educational and social measures, as part of a total treatment program.

#### How does Concerta work?

Concerta belongs to a group of medicines called central nervous system stimulants. Concerta helps increase attention and decrease impulsiveness and hyperactivity in patients with ADHD. Concerta tablet uses Osmotic Controlled-Release Oral Delivery System (OROS®) to release the medication in a controlled way throughout the day. Part of the Concerta tablet dissolves right after you / your child swallow it in the morning, giving you / your child an initial dose of medication. The rest of the medication is slowly released during the day to keep improving the symptoms of ADHD.

#### What are the ingredients in Concerta?

Medicinal Ingredients: methylphenidate hydrochloride

Non-medicinal ingredients: butylated hydroxytoluene, carnauba wax, cellulose acetate, hypromellose, lactose, phosphoric acid, poloxamer, polyethylene glycol, polyethylene oxides, povidone, propylene glycol, sodium chloride, stearic acid, succinic acid, synthetic iron oxides, titanium dioxide and triacetin

#### Concerta comes in the following dosage forms:

Extended-release tablets: 18 mg, 27 mg, 36 mg and 54 mg

**Do not use Concerta if you/your child:**

- are allergic to methylphenidate hydrochloride or any of the other ingredients in Concerta;
- have glaucoma (an eye disease with increased pressure in the eye);
- have symptomatic cardiovascular disease;
- have moderate to severe high blood pressure;
- have advanced arteriosclerosis (hardened arteries);
- have hyperthyroidism (an overactive thyroid gland); or
- are taking or have recently taken (in the past 14 days) any medications from a group called monoamine oxidase inhibitors (MAOIs)

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Concerta. Talk about any health conditions or problems you may have, including if you/your child:**

- have structural heart abnormalities, cardiomyopathy, serious heart rhythm abnormalities or other serious heart problems;
- have or have a family history of tics (movements or sounds that you cannot control) or Tourette's syndrome;
- have or have a family history of mental health problems, including:
  - psychosis,
  - mania,
  - bipolar disorder,
  - depression, or
  - suicide;
- are aggressive, anxious or agitated, or feel more aggressive, anxious or agitated than usual;
- have mild high blood pressure;
- take blood pressure medications;
- take cold, allergy or other drugs that can affect blood pressure;
- have a narrowing or blockage of your gastrointestinal tract (your esophagus, stomach, or small or large intestine);
- have a family history of sudden death or death related to heart problems;
- do strenuous exercise;
- take other medications for ADHD;
- have or have had any disorder of the blood vessels in the brain (e.g., aneurysm, stroke, vasculitis);
- have a history of drug dependence or alcoholism
- are unable to swallow tablets whole
- are pregnant, think you are pregnant or are planning to become pregnant
- are breastfeeding or plan to breastfeed. Concerta can pass through your breast milk. You should consult with your healthcare professional to determine if you should stop breastfeeding or discontinue Concerta.

**Other warnings you should know about:**

**Dependence and tolerance:** Like other stimulants, Concerta has the potential to be abused, leading to dependence and tolerance. If you have a history of drug or alcohol abuse, talk to your healthcare professional. Do not change your dose or stop taking Concerta without first talking to your healthcare professional. If you stop taking Concerta, you will need careful supervision because you may feel very depressed.

**Driving and using machines:** Concerta can affect your ability to drive and use tools or machinery. You should not drive or use tools or machinery until you know how you respond to Concerta.

**Growth in children:** Slower growth (weight gain and/or height) has been reported with long-term use of methylphenidate hydrochloride in children. Your healthcare professional will carefully watch your child's height and weight. If your child is not growing or gaining weight as expected, your healthcare professional may stop treatment.

**The following have been reported with use of Concerta and other medicines used to treat ADHD.**

**Heart-related problems:** The following heart related problems have been reported in people taking medication to treat ADHD, like Concerta:

- sudden death in patients who have heart problems or heart defects
- stroke and heart attack in adults
- increased blood pressure and heart rate

Sudden death has been reported in association with stimulant drugs for ADHD treatment in children with structural heart abnormalities. Concerta generally should not be used in children, adolescents or adults with known structural heart abnormalities.

Tell your healthcare professional if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your healthcare professional will check:

- you for heart problems before starting Concerta
- your blood pressure and heart rate regularly during treatment with Concerta

**Seek immediate medical help if you have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Concerta.**

**Mental health problems:** The following mental health problems have been reported in people taking medicine to treat ADHD like Concerta:

- new or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide actions (suicide attempt, suicidal ideation and completed suicide)
- new or worse symptoms of bipolar disorder (extreme mood swings, with periods of impulsiveness or unusual excitement, switching between periods of sadness)
- new or worse aggressive behaviour or hostility
- new psychotic symptoms (such as hearing voices, believing things that are not true, being suspicious)

These new or worse mental symptoms may be more likely to occur if you/your child have mental disorders that you may or may not know about. Tell your doctor about any mental problems or about any personal or family history of suicide, bipolar illness, or depression you or your child have.

A small number of patients taking ADHD drugs may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time during treatment, particularly at the start or during dose changes, and also after stopping Concerta.

**Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately. Close observation by a doctor is necessary in this situation.**

**Raynaud's Phenomenon:** Stimulants used to treat ADHD, such as Concerta, are associated with Raynaud's Phenomenon. During treatment with Concerta, your healthcare professional may check for problems with the circulation in your fingers and toes, including numbness, feeling cold or pain.

**Serotonin toxicity (also known as Serotonin Syndrome):** Serotonin toxicity is a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take Concerta with certain anti-depressants or migraine medications. Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

**Testing and check-ups:** Your healthcare professional may do tests before you start and during treatment with Concerta. These tests may include:

- tests that check for problems in the heart or brain
- tests that check your blood pressure and heart rate
- blood tests to check complete blood count, platelet counts and liver enzymes

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **Serious Drug Interactions**

**Do not take Concerta if you are:**

- taking or has recently taken (within the past 14 days) a monoamine oxidase inhibitor (MAOI). It may cause serious side effects.
- taking clonidine (a medicine used to treat high blood pressure). It may cause serious side effects including sudden death.

**The following may interact with Concerta:**

- alcohol;
- certain medicines for depression or anxiety, such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs);
- medicines used to manage psychosis (antipsychotic);
- certain medicines used to prevent seizures, such as phenobarbitone, phenytoin, carbamazepine and primidone;
- medicines used to prevent blood clots (commonly called "blood thinners"), such as warfarin;
- medicines used to increase blood pressure;
- medicines used to treat high blood pressure;
- anesthetics on the day of an operation, as there is a chance of a sudden rise in blood pressure and heart rate during the operation.

### **How to take Concerta:**

- **Do not chew, crush, or divide the tablets.** Swallow Concerta tablets whole with water or other liquids, such as milk or juice.
- Take Concerta once each day in the morning with or without food.
- The Concerta tablet does not dissolve completely after all the drug has been released, and you / your child may sometimes notice it in your / your child's stool. Do not be concerned, this is normal.
- As with all medicines, never share Concerta with anyone else.

### **Usual dose:**

Your healthcare professional will decide the dose that is right for you/your child. Always follow the directions of your healthcare professional and never change the dose or stop taking Concerta without discussing it with your healthcare professional first.

Take Concerta in the morning exactly as prescribed. Your healthcare professional may adjust the dose until it is right for you / your child. From time to time, your healthcare professional may interrupt your / your child's treatment to check your / your child's symptoms while you / your child are not taking the drug.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much Concerta, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### **Missed Dose:**

If you forget to take your dose in the morning, wait until the next day and take the usual dose at the usual time in the morning. Do not take an afternoon dose. Do not double the dose to make up for the missed dose.

### **What are possible side effects from using Concerta?**

These are not all the possible side effects you may have when taking Concerta. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- headache
- sleeplessness
- dizziness
- nervousness
- anxiety
- irritability
- tics
- decreased appetite
- weight loss
- stomach pain

- nausea
- vomiting
- dry mouth
- fast heart rate
- increased sweating
- difficulty opening the mouth (trismus)
- inability to control excretion of urine (incontinence)
- nosebleed
- enlarged breasts in boys or men

| <b>Serious side effects and what to do about them</b>  |   |                     |  |
|--|---|---------------------|--|
| <b>Symptom / effect</b>  | <b>Talk to your healthcare professional</b> |                     | <b>Stop taking drug and get immediate medical help</b> |
|  | <b>Only if severe</b>                       | <b>In all cases</b> |  |
| <b>COMMON</b>  |   |                     |  |
| Aggressive behaviour or hostility  |   | ✓                   |  |
| Blurred vision   |   | ✓                   |  |
| <b>Hypertension</b> (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or fast or uneven heartbeat. | ✓   |                     |  |
| <b>RARE</b>  |   |                     |  |
| <b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, swelling of the face, lips, tongue or throat, hives or rash.   |   |                     | ✓  |
| <b>VERY RARE</b>   |   |                     |  |
| <b>Cerebrovascular disorders</b> (problems with the blood vessels in the brain): severe headaches, weakness or paralysis of any body part, or problems with coordination, vision, speaking, finding words or with your memory, stroke    |   |                     | ✓  |
| <b>Heart problems:</b> fast or uneven heartbeat, chest pain, difficulty breathing, fainting  |   | ✓                   |  |
| <b>Liver failure:</b> yellowing of the skin or whites of the eyes (jaundice), bleeding easily, swollen abdomen, mental disorientation or confusion, sleepiness, coma   |   | ✓                   |  |

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|  | <b>Only if severe</b>                       | <b>In all cases</b> |  |
| <b>New or worsening mental health problems:</b> paranoia, delusions, hallucinations (seeing, feeling or hearing things that are not there), mania (feeling unusually excited, over-active, or uninhibited) |   | ✓                   |  |
| <b>Priapism:</b> long-lasting (greater than 4 hours in duration) and painful erection of the penis   |   |                     | ✓  |
| <b>Rhabdomyolysis</b> (breakdown of damaged muscle): muscle weakness, muscle pain, muscle spasms, red-brown coloured urine   |   | ✓                   |  |
| <b>Seizures</b> (fits): uncontrollable shaking with or without loss of consciousness   |   |                     | ✓  |
| <b>Suicidal behaviour:</b> thoughts or actions about hurting or killing yourself.  |   |                     | ✓  |
| <b>UNKNOWN</b>   |   |                     |  |
| <b>Raynaud's phenomenon</b> (episodes of reduced blood flow): cold feeling in fingers and toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue  |   | ✓                   |  |

*If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.*

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Store Concerta in a safe place at room temperature (between 15-30°C). To protect Concerta from moisture, do not store this medicine in hot, damp or humid places.

Keep out of reach and sight of children.

**If you want more information about Concerta:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drugproduct-database.html>); the manufacturer's website [www.janssen.com/canada](http://www.janssen.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

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