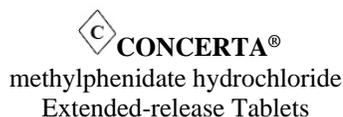


PART III: CONSUMER INFORMATION



This leaflet is part III of a three-part “Product Monograph” published when CONCERTA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CONCERTA®. Contact your doctor or pharmacist if you have any questions about the drug.

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

Please read this before you/your child start taking CONCERTA® tablets. Remember, this information does not take the place of your doctor’s instructions.

ABOUT THIS MEDICATION

What the medication is 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 a central nervous system stimulant. CONCERTA® contains a medicinal ingredient that has been used to treat ADHD for more than 30 years.

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.

Symptoms of ADHD in adults may include a lack of organization, problems starting tasks, impulsive actions, daydreaming, slow processing of information, difficulty learning new things, irritability, lack of esteem and excessive effort to maintain some organization.

What it does:

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. CONCERTA® helps increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

When it should not be used:

You / your child should NOT take CONCERTA® if you / your child:

- are allergic to methylphenidate hydrochloride or any of the other ingredients in CONCERTA®;
- have glaucoma, an eye disease
- 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 taken within the past 14 days monoamine oxidase inhibitors (a type of drug, see **INTERACTIONS WITH THIS MEDICATION**).

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

What the medicinal ingredient is:

methylphenidate hydrochloride

What the nonmedicinal ingredients are:

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

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **Drug Dependence**
Abuse of CONCERTA® 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

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

1. Heart-related problems:

- **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 doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor may wish to check you or your child carefully for heart problems before starting CONCERTA®.

Your doctor may wish to check you or your child's blood pressure and heart rate regularly during treatment with CONCERTA®.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking CONCERTA®.

2. Mental (Psychiatric) problems:

- **New or worse thoughts or feelings related to suicide (thinking about or feeling like killing oneself) and suicide actions (including suicide attempt, suicidal ideation and completed suicide)**
- **new or worse symptoms of bipolar illness, characterized by extreme mood swings, with periods of mania (unusually excited, over-active or un-inhibited) alternating with periods of depression (feelings of sadness, worthlessness or hopelessness)**
- **new or worse aggressive behaviour or hostility**
- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

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.**

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking CONCERTA®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

BEFORE you or your child uses CONCERTA®, talk to your doctor or pharmacist if you / your child:

- have structural heart abnormalities;
- have tics (movements or sounds that you cannot control) or Tourette's syndrome, or if someone in your

- family has tics or Tourette's syndrome;
- have eye problems, such as:
 - increased pressure in the eye
 - far-sightedness (difficulty seeing near objects)
- have mental problems or family history of mental problems, including psychosis, mania, bipolar illness, depression or suicide;
- become 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 drugs for ADHD;
- have or have had any disorder of the blood vessels in the brain (e.g., aneurysm, stroke, vasculitis), or
- have circulation problems in fingers and toes, including numbness; feeling cold or pain. (This is also known as Raynaud's).

Tell your doctor *immediately* if you / your child develop any of the above conditions or symptoms while taking CONCERTA®. He/she will decide if you can start/continue taking CONCERTA®.

BEFORE taking CONCERTA®, tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if you are nursing a baby. Methylphenidate passes into breast milk. If you take CONCERTA®, it can be in your breast milk. You should consult with your doctor to determine whether you should stop breast-feeding or discontinue CONCERTA®.

Your doctor will monitor your progress with CONCERTA® and may require you to do occasional tests to ensure your health and safety.

INTERACTIONS WITH THIS MEDICATION

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

- type of medicine for depression or anxiety called a 'selective serotonin reuptake inhibitor' (SSRI) or a 'serotonin and norepinephrine reuptake inhibitor' (SNRI);
- clonidine;
- other medicines that a doctor has prescribed;
- medicines that you buy yourself without a prescription
- any herbal remedies that you /your child may be taking.

You / your child 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.

You should avoid alcoholic drinks while taking CONCERTA®.

CONCERTA® may change the way your / your child's body reacts to certain medicines. These include medicines used to treat depression (e.g., amitriptyline, imipramine and fluoxetine), prevent seizures (e.g., phenobarbitone, phenytoin, carbamazepine and primidone) or prevent blood clots (commonly called "blood thinners", e.g., warfarin). Your doctor may need to change your / your child's dose of these medicines if you / your child are taking them with CONCERTA®.

PROPER USE OF THIS MEDICATION

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.

CONCERTA® has not been studied and should not be used in children under six years of age. CONCERTA® has not been studied in adults over 65 years of age.

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. This is normal.

CONCERTA® may be a part of your / your child's overall treatment for ADHD. Your doctor may also recommend that you / your child have counselling or other therapy.

As with all medicines, never share CONCERTA® with anyone else.

Usual dose:

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

Overdose:

In case of a drug overdose, immediately go to the nearest emergency room even if you do not feel sick. Make sure you take your medicine bottle with you to show the doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Refer to the beginning of this leaflet for information on reported heart-related and mental (psychiatric) problems.

In the clinical studies with patients using CONCERTA®, the very common side effects (may affect more than 1 in 10 people) were headache, stomach pain, sleeplessness, dry mouth, nausea (feeling sick) and decreased appetite. Other side effects commonly seen with CONCERTA® (may affect up to 1 in 10 people) include vomiting, fast heart rate, weight loss, anxiety, irritability, increased sweating, dizziness, nervousness, tics, increased blood pressure. Tell your doctor if you / your child have blurred vision when taking CONCERTA®.

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

Stimulants may impair your / your child's ability to operate potentially hazardous machinery or vehicles. You should exercise caution until you are reasonably certain that CONCERTA® does not adversely affect your / your child's ability to engage in such activities.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	Call your doctor right away		Stop taking drug and seek immediate emergency medical assistance
	Only if severe	In all cases	
Very Rare			
Signs of heart problems, such as chest pain, shortness of breath, or fainting		✓	
Convulsions (seizures)			✓
Persistent (greater than 4 hours in duration) and painful erections (priapism)			✓
New or worsening psychotic or manic symptoms: -Paranoia, delusions -Hallucinations: seeing, feeling or hearing things that are not real -Mania: feeling unusually excited, over-active, or uninhibited (see Warnings and Precautions)		✓	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect	Call your doctor right away		Stop taking drug and seek immediate emergency medical assistance
	Only if severe	In all cases	
Suicidal behaviour: Thoughts or actions about hurting or killing yourself. (see Warnings and Precautions)			✓
Liver damage or sudden liver failure. Symptoms may include yellowing of the whites of the eyes, or of the skin, dark urine, bleeding, mental clouding (feeling like you're in a fog), confusion.		✓	
Problem with blood vessels in the brain (such as inflamed blood vessels, stroke caused by a burst blood vessel or blocked blood supply to the brain). Symptoms may include severe headaches, weakness or paralysis of any body part, or problems with coordination, vision, speaking, finding words or with your memory.			✓
Rare			
Symptoms of allergic reaction, such as itching, skin rash, swelling of the mouth, face, lips, or tongue, or shortness of breath.			✓
Common			
Aggressive behaviour or hostility		✓	
Unknown			
Raynaud's Phenomenon: discoloration of the fingers and toes, pain, sensations of cold and/or numbness		✓	

This is not a complete list of side effects. For any unexpected effects while taking CONCERTA®, contact your doctor or pharmacist.

HOW TO STORE IT

CONCERTA® should be stored in a safe place at room temperature (between 15-30°C). Do not store this medicine in hot, damp or humid places.

Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator **1908C**
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.

NOTE: Should you require information related to the management of the side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full Product Monograph go to: www.janssen.com/canada or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

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