
CONSUMER MEDICINE INFORMATION

CONCERTA[®] extended-release tablets

What is in this leaflet

This leaflet answers some common questions about Concerta extended-release tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking Concerta against the benefits this medicine is expected to have for you or your child.

If you have any concerns about taking Concerta ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What is Concerta used for

Concerta is used to treat Attention Deficit Hyperactivity Disorder (ADHD).

Concerta is part of a comprehensive treatment program, which usually includes psychological, educational and social therapy.

Concerta is a stimulant that increases attention and decreases impulsiveness and hyperactivity in patients with ADHD.

The tablets are made in an extended release form. This means that they release the active ingredient slowly. The outer layer of the tablet dissolves right after it is swallowed in the morning, giving an initial dose of methylphenidate hydrochloride.

The tablets have a special shell that allows the rest of the methylphenidate hydrochloride to be released from the tablet at a slow rate throughout the day.

The tablet shell does not dissolve completely after all the drug has been released and sometimes the tablet shell may be seen in your stool. This is normal.

Your doctor may have prescribed Concerta for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you/your child.

Before you take it

When you must not take it

Do not take Concerta if you/your child have an allergy to:

- methylphenidate hydrochloride (the active ingredient in Concerta) or
- any of the other ingredients in Concerta. See **Product Description** at the end of this leaflet for a list of ingredients.

Symptoms of an allergic reaction may include: rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.

Do not take Concerta if you/your child have any of the following medical conditions:

- overactive thyroid gland
- heart problems, including severe angina (chest pain), irregular heart beat and high blood pressure (untreated or not under control)
- severe depression or other mental illness
- currently taking or have taken a MOA inhibitor (eg phenelzine, trancypromine) or medicines used in Parkinson's disease (eg. selegiline) within the last 14 days
- have a history of drug or alcohol abuse.

Do not take it if the packaging is torn or shows signs of tampering.

Do not take it beyond the expiry date (month and year) printed on the pack. If you/your child take it after the expiry date it may not work.

Before you/your child start to take it

You must tell your doctor if you/your child:

- are pregnant or planning to become pregnant
- are breastfeeding or wish to breastfeed as methylphenidate passes into breast milk
- have a problem with the blood vessels in your brain (such as an aneurysm)
- develop severe headaches, weakness or paralysis of any body part, or develop problems with coordination, vision, speaking, finding words or with your memory.
- are or have been alcohol or drug dependent
- have/has high blood pressure
- have/has a narrowing or blockage in your digestive tract (stomach, small or large intestine)
- have Tourette's syndrome (tics) or a family history of this disorder
- have/has eye problems such as glaucoma (increased pressure in the eye)
- Far-sightedness (difficulty seeing near objects)
- Become aggressive, anxious or agitated, or feel more aggressive, anxious or agitated than usual

Your doctor may need to adjust the dose or adapt your treatment if you/your child have any of these conditions.

If you have not told your doctor or pharmacist about any of the above, tell them before you/your child start taking Concerta.

Taking other medicines:

Tell your doctor or pharmacist if you/your child are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you/your child are taking any of the following:

- Monoamine oxidase (MOA) inhibitors such as phenelzine
- medicines that increase blood pressure
- Selective Serotonin Reuptake Inhibitors (SSRIs), medicines used to treat depression, obsessive compulsive disorders and anxiety disorders such as fluoxetine, fluvoxamine, citalopram, escitalopram, paroxetine and sertraline

These medicines may be affected by Concerta or may affect how well Concerta works. Your doctor or pharmacist can tell you what to do if you/your child are taking any of these medicines.

How to take it

Follow the directions given to you by your doctor and pharmacist. These directions may differ from the information contained in this leaflet.

Concerta should be swallowed whole with a glass of liquid. It should not be chewed, broken or crushed. Concerta may be taken with or without food.

How much to take:

If you/your child are currently taking other formulations of methylphenidate, your doctor will decide the best starting dose.

Adolescents and Children over 6 years

- The starting dose is one 18 mg tablet in the morning
- The maximum dose for children aged from 6 to 12 years is 54 mg a day and the maximum dose for adolescents aged from 13 to 18 years is 72 mg a day, taken as one dose.

Adults

- The starting dose is one CONCERTA 18 mg or 36 mg extended-release tablet in the morning
- The maximum dose is 72 mg a day taken as one dose.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you/your child forget to take it

- It may be best to wait until the following morning to take the next dose. Remember the effects of Concerta are designed to last approximately 12 hours from the time it is taken.
- Do not take or give your child a double dose to make up for the dose missed.

If you/your child have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you/your child have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You/your child may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy.

If you/your child take too much Concerta you/your child may experience symptoms such as vomiting, headache, irregular heart beat, dilated pupils, breathing problems, confusion and seizures.

While you are using it

Things you must do

- Always follow your doctor's instructions carefully
- Take Concerta exactly as your doctor has prescribed. Like all stimulants, Concerta may become habit-forming and can be abused by some people. If you/your child take it correctly as instructed by your doctor, abuse or dependence should not be a problem, either now or later in life
- Have your child's height and weight checked regularly as CONCERTA may slow children's rate of growth
- Be sure to keep all of your doctor's appointments so that your/your child's progress can be checked
- Your doctor will want to check your/your child's blood pressure and do blood test from time to time to prevent unwanted side effects from happening
- Tell your doctor if you become pregnant while taking Concerta
- If you/your child are about to start taking a new medicine, tell your doctor and pharmacist that you/your child are taking Concerta.
- If you/your child develop prolonged and painful erections, seek immediate medical attention.

Things you must not do

- Do not use Concerta to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar.
- **Do not stop treatment without first checking with your doctor.** If you/your child suddenly stop taking this medicine, you/your child's condition may reappear or you/your child may get unwanted effects such as depression. Your doctor may want to gradually reduce the amount of medicine taken each day before stopping it completely.

Things to be careful of

- Concerta may impair your ability to operate potentially hazardous machinery or vehicles. You should exercise caution until you are reasonably certain how you react to Concerta before you drive a car, operate machinery, or do anything else that could be dangerous.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You/your child may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You/your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you/your child experience any of the following and they worry you:

stomach or bowel problems such as:

- loss of appetite
- stomach pain

difficulty thinking or working because of:

- headache
- trouble sleeping

- dizziness

throat or lung infections such as:

- cold
- sore throat and hoarse/ loss of voice
- feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell

joints or movement changes such as:

- painful and/ or swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise

growth issues with your child such as:

- reduced weight gain and/or height

Tell your doctor immediately if you notice any of the following:

reproductive system disorders:

- prolonged and painful erections

behavioural changes such as:

- aggression
- confusion
- disorientation
- seeing, feeling or hearing things that are not there
- mood swings, overexcitement over-activity and uninhibited behaviour
- nervousness
- restlessness

nervous system changes such as:

- convulsions, fits or seizures
- muscle twitching

changes in your sight, namely:

- visual disturbance
- blurred or double vision
- dilated pupils

changes to the skin or hair such as:

- unusual hair loss or thinning of the hair
- redness of the skin
- excessive sweating
- signs of allergy such rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body

body temperature changes such as:

- fever
- abnormally high body temperature

heart or blood problems such as:

- fast or abnormal heart beat
- increased blood pressure
- chest pain
- chest discomfort
- low white blood cell count

- low platelet count
- 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).

problems such as:

- liver disease
- sudden liver failure

Other side effects include:

- slowing of growth (height and weight) in children
- blockage of the oesophagus, stomach, small or large intestine in patients who already have a narrowing in any of these organs

Common side effects include:

- decreased appetite
- dry mouth
- nausea
- weight loss
- irritability
- weakness
- muscle spasm
- brief periods of acute anxiety where symptoms being suddenly and usually include difficulty breathing, chest pains, fast heart rate, dizziness and light-headedness, sweating, trembling and faintness
- hot flushes
- increased levels of the liver enzyme ALT.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After using it

Storage

Keep the tablets in the bottle until it is time to take them.

Store in a cool dry place where the temperature is below 25°C. Keep the container tightly closed.

Keep medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store Concerta, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you/your child to stop taking CONCERTA extended-release tablets or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine that may be left over.

Product Description

What it looks like

You can identify Concerta tablets by their colour and shape. This is important because each type of tablets, contains a different amount of the active methylphenidate hydrochloride:

18 mg: Yellow capsule-shaped tablets, with “alza 18” printed in black ink on one side

27 mg: Grey capsule-shaped tablets, with “alza 27” printed in black ink on one side

36 mg: White capsule-shaped tablets, with “alza 36” printed in black ink on one side

54 mg: Brownish-red capsule-shaped tablets, with “alza 54” printed in black ink on one side.

Ingredients

Each CONCERTA extended-release tablet contains 18 mg, 27 mg, 36 mg or 54 mg of methylphenidate hydrochloride as the active ingredient.

Each tablet also contains the following other ingredients: butylated hydroxytoluene, carnauba wax, cellulose acetate, hypromellose, Opacode black NS-78-17715, Opadry clear YS-1-19025-A, phosphoric acid, poloxamer, polyethylene oxide, povidone, sodium chloride, stearic acid, succinic acid and synthetic iron oxides. The 18 mg tablet also contains Opadry II yellow YS-30-12788-A. The 27 mg tablet also contains Opadry II grey Y-30-17528. The 36 mg tablet also contains Opadry II white Y-30-18037. The 54 mg tablet also contains Opadry II red Y-30-15567-A.

The tablets contain lactose.

Sponsor

Janssen-Cilag (New Zealand) Ltd

Auckland, New Zealand

Telephone: 0800 800 806

This leaflet was prepared on September 2017.