



The tablet should be swallowed whole and not chewed, broken, or crushed. The tablet may be taken with or without food.

The tablet does not dissolve completely after all of the drug has been released and sometimes the tablet shell may appear in your stools. This is normal.

**Use in children aged 6 years and over**

- the recommended starting dose of Concerta XL is 18 mg once daily for children who are not currently taking methylphenidate, or for children who are switching from another stimulant to methylphenidate.
- the maximum daily dose is 54 mg.

**Use in adults**

- the maximum daily dose in adults is 72 mg.

**For adults who have taken Concerta XL before:**

- if you have already taken Concerta XL as a child or adolescent, the same daily dosage (mg/day) can be used; your doctor will check regularly to see if any adjustment is required.

- adult patients may require a higher daily dosage but the doctor will aim to give you the lowest dose that is effective.

**For adults who have not taken Concerta XL before:**

- the recommended starting dose is 18 mg daily.

**If you do not feel better after 1 month of treatment**

If you do not feel better after 1 month of treatment, tell your doctor. Your doctor may decide that you need a different treatment.

**Not using Concerta XL properly**

If Concerta XL is not used properly, this may cause abnormal behaviour. It may also mean that you start to depend on the medicine. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

This medicine is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

**If you take more Concerta XL than you should**

If you take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Medical treatment might be needed.

Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

**If you forget to take Concerta XL**

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

**If you stop taking Concerta XL**

If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Concerta XL.

**Things your doctor will do when you are on treatment**

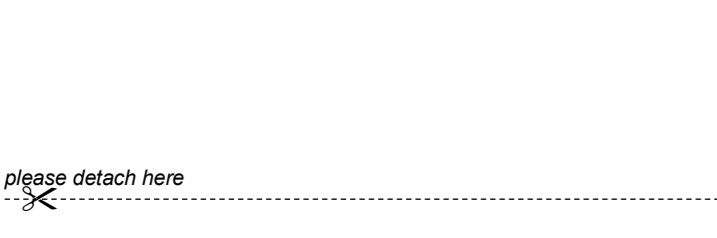
Your doctor will do some tests

- before you start - to make sure that Concerta XL is safe and will be of benefit.
- after you start - they will be done at least every 6 months, but possibly more often. They will also be done when the dose is changed.
- these tests will include:
  - checking your appetite
  - measuring height and weight
  - measuring blood pressure and heart rate
  - checking whether you have any problems with your mood, state of mind or any other unusual feelings. Or if these have got worse while taking Concerta XL.

Long-term treatment

Concerta XL does not need to be taken for ever. If you take Concerta XL for more than a year, your doctor should stop treatment for a short time, this may happen during a school holiday. This will show if the medicine is still needed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.



**Some people need to talk to their doctor before they start having this medicine**

You need to talk to your doctor if:

- you have epilepsy (fits)
- you are pregnant or breastfeeding
- you are taking other medicines – your doctor needs to know about all the medicines you are taking.

**How do I take my medicine?**

- swallow your medicine with water.
- your doctor will tell you how many times a day you should take your medicine

#### 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Although some people get side effects, most people find that methylphenidate helps them. Your doctor will talk to you about these side effects.

**Some side effects could be serious. If you have any of the side effects below, see a doctor straight away: Common (may affect up to 1 in 10 people)**

- uneven heartbeat (palpitations)
- mood changes or mood swings or changes in personality
- Uncommon (may affect up to 1 in 100 people)**
- thinking about or feeling like killing yourself
- seeing, feeling, or hearing things that are not real, these are signs of psychosis
- uncontrolled speech and body movements (Tourette's)
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

**Rare (may affect up to 1 in 1,000 people)**

- feeling unusually excited, over-active and un-inhibited (mania)

**Very rare (may affect up to 1 in 10,000 people)**

- heart attack
- sudden death
- suicidal attempt
- fits (seizures, convulsions epilepsy)
- skin peeling or purplish red patches
- inflammation or blocked arteries in the brain
- temporary paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain)
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other drugs that may be taken in combination with methylphenidate.
- Not known (frequency cannot be estimated from the available data)**
- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- prolonged erections, sometimes painful or an increased number of erections.

If you have any of the side effects above, see a doctor straight away.

**Other side effects include the following, if they get serious, please tell your doctor or pharmacist:**

**Very common (may affect more than 1 in 10 people)**

- headache
- feeling nervous
- not being able to sleep.

**Common (may affect up to 1 in 10 people)**

- joint pain
- blurred vision
- tension headache
- dry mouth, thirst
- trouble falling asleep
- high temperature (fever)
- decreased sex drive
- unusual hair loss or thinning
- muscle tightness, muscle cramps
- loss of appetite or decreased appetite
- inability to develop or maintain an erection
- itching, rash or raised red itchy rashes (hives)
- feeling unusually sleepy or drowsy, feeling tired
- excessive teeth grinding (bruxism)
- feeling of panic
- tingling feeling, prickling, or numbness of the skin
- increased alanine aminotransferase (liver enzyme) level in your blood
- cough, sore throat or nose and throat irritation; upper respiratory tract infection; sinus infection



- do not stop taking the medicine without talking to your doctor first.

**Possible side effects**

Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult you trust straight away. They can then talk to your doctor. The main things that could affect you are:

- feeling worried or nervous
- feeling dizzy, or getting head aches
- being very depressed and unhappy or wanting to hurt yourself
- having different moods than usual, not being able to get to sleep
- skin rashes, bruising easily, getting out of breath

- high blood pressure, fast heart beat (tachycardia)
- dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour
- upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.
- excessive sweating
- weight decreased

**Uncommon (may affect up to 1 in 100 people)**

- dry eyes
- constipation
- chest discomfort
- blood in the urine
- listlessness
- shaking or trembling
- increased need to pass urine
- muscle pain, muscle twitching
- shortness of breath or chest pain
- feeling hot
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping.

**Rare (may affect up to 1 in 1,000 people)**

- problems with sex drive
- feeling disorientated or confused
- trouble seeing or double vision
- swelling of the breasts in men
- redness of the skin, red raised skin rash
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

**Very rare (may affect up to 1 in 10,000 people)**

- muscle cramps
- small red marks on the skin
- abnormal liver function including sudden liver failure and coma
- changes in test results – including liver and blood tests
- abnormal thinking, lack of feeling or emotion
- cold feeling in the arms and legs
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').

**Not known (frequency cannot be estimated from the available data)**

- migraine
- dilated pupils
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true
- severe stomach pain, often with feeling and being sick
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering
- nosebleed.

**Effects on growth**

When used for more than a year, methylphenidate may cause reduced growth in some children. This affects less than 1 in 10 children.

- there may be lack of weight gain or height growth.
- your doctor will carefully watch your height and weight, as well as how well you are eating.
- if you are not growing as expected, then your treatment with methylphenidate may be stopped for a short time.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5 How to store Concerta XL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture. Do not store above 30°C.

The pack contains one or two silica gel pouches. These pouches are used to keep the tablets dry and should not be eaten.

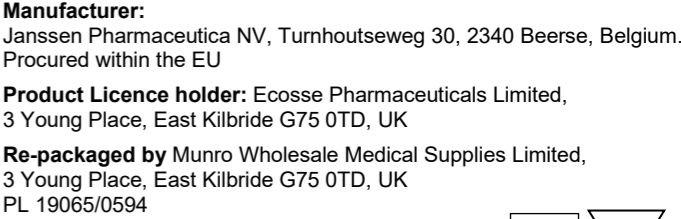
If the tablets become discoloured or show any signs of deterioration, consult your pharmacist who will advise you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

#### 6 Contents of the pack and other information

- What Concerta XL contains**
- The active substance is methylphenidate hydrochloride
- Each tablet contains 54mg methylphenidate hydrochloride.
- The other ingredients are:
  - butylhydroxytoluene (E321), cellulose acetate, hypromellose (E464), phosphoric acid 85%, poloxamer 188, macrogol 200K and 7000K, povidone K29-32, sodium chloride, stearic acid, succinic acid, iron oxide black (E172), iron oxide yellow (E172) and iron oxide red (E172).
- Film coat:** hypromellose (E464), lactose monohydrate, titanium dioxide (E171), triacetin, iron oxide yellow (E172) and iron oxide red (E172)
- Clear coat:** carnauba wax, hypromellose (E464), macrogol 400.
- Printing Ink:** iron oxide black (E172), hypromellose (E464), and propylene glycol.

- What Concerta XL looks like and contents of the pack**
- Capsule-shaped brownish-red tablet with 'alza 54' printed on one side in black ink.
- The medicinal product is available in bottles containing 30 prolonged-release tablets.

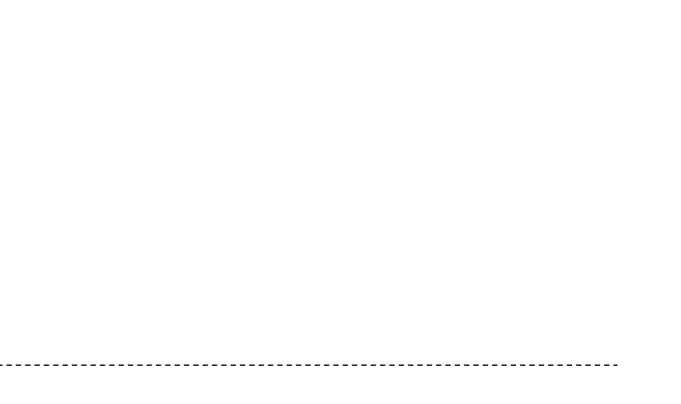


This leaflet was revised in 24.06.2025
E0594/6 11.24
Concerta® is a registered trademark

POM

CD

## If you are blind or partially sighted and require this leaflet in a different format, call 01355 574450 and ask for the Regulatory Department.



- the medicine is special for you - **do not let anyone else have it**. It may help you, but it could hurt someone else.
  - if you forget to take your medicine don't take two tablets the next time. Just take one tablet at the next normal time.
  - if you do take too much medicine, tell your mum, dad or carer **right away**.
  - it is important not to take too much medicine or you will get ill.
  - don't stop taking your medicine until your doctor says it's OK.
- Who should I ask if there is anything I don't understand?**
Your mum, dad, carer, doctor, nurse or pharmacist will be able to help you.