

Package Leaflet: Information for the user
Concerta® XL 18 mg Prolonged Release Tablets
Concerta® XL 36 mg Prolonged Release Tablets

Methylphenidate hydrochloride

The name of your medicine is Concerta XL, it contains the active substance 'methylphenidate hydrochloride'.
The name 'methylphenidate' will also be used in this leaflet.

Important things you need to know about your medicine

This medicine is used to treat ADHD

- The full name for ADHD is 'Attention Deficit Hyperactivity Disorder'.
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other treatments for ADHD as well as this medicine.

Read Section 1 for more information.

Before you take this medicine, talk to your doctor if:

- You have heart, circulation, or mental health problems - you may not be able to take this medicine.
- You are taking any other medicines - this is because methylphenidate can affect how other medicines work.

Read Section 2 for more information.

While taking this medicine:

- See your doctor regularly. This is because your doctor will want to check how the medicine is working.
- Do not stop taking the medicine without first talking to your doctor.
- Your doctor may stop your medicine to see if it is still needed, if you take it for more than a year.
- The most common side effects are feeling nervous, not being able to sleep or having a headache.

Read Sections 3 and 4 for more information.

Talk to your doctor straight away if any of the following happen:

- Your mood and how you feel changes.
- You feel any problems with your heart.

Read Section 4 for more information.

The rest of this leaflet includes more detail and other important information on the safe and effective use of this medicine.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you only. Do not pass it on to others.
- It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The leaflet has been written in sections:

- Sections 1 to 6 are for parents and carers (sometimes called 'your guardians').
- The last section is a special section for a child or young person to read.

However, all sections are written as though the child or young person taking the medicine is reading them.

The sections are:

- 1. What Concerta XL is and what it is used for**
- 2. What you need to know before you take Concerta XL**
- 3. How to take Concerta XL**
- 4. Possible side effects**
- 5. How to store Concerta XL**
- 6. Contents of the packet and other information**

Information for children and young people

Now read the rest of this leaflet before you start taking this medicine because it contains important information for you.

1 What Concerta XL is and what it is used for

What it is used for

Concerta XL is used to treat 'attention deficit hyperactivity disorder' (ADHD).

- it is used in children and young people between the ages of 6 and 18.
- it is used only after trying treatments which do not involve medicines. Such as counselling and behavioural therapy.

Concerta XL is not for use as a treatment for ADHD in children under 6 years of age or for the initiation of treatment in adults. When treatment was started at a younger age, it might be appropriate to continue taking Concerta XL when you become an adult.

Your doctor will advise you about this.

How it works

Concerta XL improves the activity of certain parts of the brain which are under-active.

The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes:

- psychological
- educational and
- social therapy.

It is prescribed only by doctors who have experience in children or young people's behaviour problems. Although there is no cure for ADHD, it can be managed using treatment programmes.

About ADHD

Children and young people with ADHD find it:

- hard to sit still and
- hard to concentrate.

It is not their fault that they cannot do these things.

Many children and young people struggle to do these things. However, with ADHD they can cause problems with everyday life.

Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places.

ADHD does not affect the intelligence of a child or young person.

2 What you need to know before you take Concerta XL

Do not take Concerta XL if:

- you are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- you have a thyroid problem
- you have increased pressure in your eye (glaucoma)
- you have a tumour of your adrenal gland (phaeochromocytoma)
- you have an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
- you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- you have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or were born with a heart problem
- you have had a problem with the blood vessels in your brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- you are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor)- see 'Other medicines and Concerta XL'
- you have mental health problems such as:
 - a 'psychopathic' or 'borderline personality' problem
 - abnormal thoughts or visions or an illness called 'schizophrenia'
 - signs of a severe mood problem like:
 - o feeling like killing yourself
 - o severe depression, where you feel very sad, worthless and hopeless
 - o mania, where you feel unusually excitable, over-active, and un-inhibited.

Do not take methylphenidate if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

Talk to your doctor before taking Concerta XL if:

- you have liver or kidney problems
- you have a problem with swallowing or swallowing whole tablets
- you have a narrowing or blockage of your gut or food-pipe
- you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- you have ever abused or been dependent on alcohol, prescription medicines or street drugs
- you are a girl and have started your periods (see the 'Pregnancy, breast-feeding and contraception' section below)
- you have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- you have high blood pressure
- you have a heart problem which is not in the 'Do not take' section above
- you have a mental health problem which is not in the 'Do not take' section above.

Other mental health problems include:

- mood swings (from being manic to being depressed - called 'bipolar disorder')
- starting to be aggressive or hostile, or your aggression gets worse
- seeing, hearing or feeling things that are not there (hallucinations)
- believing things that are not true (delusions)
- feeling unusually suspicious (paranoia)
- feeling agitated, anxious or tense
- feeling depressed or guilty.

Tell your doctor or pharmacist if any of the above apply to you before starting treatment.

This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you.

Checks that your doctor will make before you start taking Concerta XL

These checks are to decide if methylphenidate is the correct medicine for you.

Your doctor will talk to you about:

- any other medicines you are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you are feeling, such as feeling high or low, having strange thoughts or if you have had any of these feelings in the past
- whether there is a family history of 'tics' (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behaviour problems you or other family members have ever had.

Your doctor will discuss whether you are at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check your mental health history, and check if any of your family have a history of suicide, bipolar disorder or depression.

It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Other medicines and Concerta XL

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Do not take methylphenidate if you:

- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in your blood pressure.

If you are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you are taking any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:

- other medicines for depression
- medicines for severe mental health problems
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain medicines that can affect blood pressure.

It is important to check with your pharmacist when you buy any of these products

- medicines that thin the blood to prevent blood clots.

If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Having an operation

Tell your doctor if you are going to have an operation. You should not take methylphenidate on the day of your surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

Drug testing

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

Concerta XL with alcohol

Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy, breast-feeding and contraception

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is not known if methylphenidate will affect an unborn baby. Tell your doctor or pharmacist before using methylphenidate if you are:

- having sex. Your doctor will discuss contraception with you
- pregnant or think you may be pregnant. Your doctor will decide whether you should take methylphenidate.
- breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk. Therefore, your doctor will decide whether you should breast-feed while taking methylphenidate.

Driving and using machines

You may feel dizzy, have problems focussing or have blurred vision when taking methylphenidate. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected.

Concerta XL contains lactose

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3 How to take Concerta XL

How much to take

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- your doctor will usually start treatment with a low dose and increase it gradually as required.
- the maximum daily dose is 54 mg.
- you should take Concerta XL once each day in the morning with a glass of water.

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.

If you do not feel better after 1 month of treatment

If you do not feel better, tell your doctor. They may decide 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.

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.

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
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system -due to a temporary lack of blood supply to the brain
- 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)
- paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain)

If

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)
- problems with 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
- clenching or grinding your teeth, 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
- 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.

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)

- feeling disorientated or confused
- trouble seeing or double vision
- swelling of the breasts in men
- excessive sweating, redness of the skin, red raised skin rash.

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

- muscle cramps
- small red marks on the skin
- abnormal liver function including liver failure and coma
- changes in test results – including liver and blood tests
- abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- 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

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: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website:

www.hpra.ie, E-mail: medsafety@hpra.ie

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.

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

- Concerta XL 18mg Prolonged Release Tablets contain 18mg of methylphenidate hydrochloride.
- Concerta XL 36mg Prolonged Release Tablets contain 36mg of methylphenidate hydrochloride.

The other ingredients are:

- butylhydroxytoluene (E321), cellulose acetate, hypromellose (E464), phosphoric acid concentrated, poloxamer 188, polyethylene oxides 200K and 7000K, povidone K29-32, sodium chloride, stearic acid, succinic acid, iron oxide black (E172) and iron oxide yellow (E172).
- **Film coat:** hypromellose (E464), lactose monohydrate, titanium dioxide (E171), triacetin, iron oxide yellow (E172, 18 mg tablets only) and stearic acid (18 mg tablet only).
- **Clear coat:** carnauba wax, hypromellose (E464), macrogol 400.
- **Printing Ink:** iron oxide black (E172), hypromellose (E464), isopropyl alcohol, propylene glycol and purified water.

What Concerta XL looks like and contents of the pack

Concerta XL is available in two strengths: 18 mg and 36 mg. Each capsule shaped tablet is individually marked to aid identification:

- 18 mg: Yellow, with 'alza 18' printed on one side in black ink.
- 36 mg: White with 'alza 36' printed on one side in black ink.

The medicinal product is available in bottles containing 30 prolonged-release tablets.

Parallel Product Authorisation Numbers:

Concerta XL 18mg Prolonged-release Tablets PPA 465/417/1

Concerta XL 36mg Prolonged-release Tablets PPA 465/417/2

Product procured from within the EU, repackaged and distributed by the parallel product authorization holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Manufacturer

Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340, Beerse, Belgium.

Concerta is a registered trademark of Alza Corporation.

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Information for children and young people

This info is to help you learn the main things about your medicine called Concerta XL.

If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.

It may help if you read small bits at a time.

Why have I been given this medicine?

This medicine can help children and young people with 'ADHD'.

- ADHD can make you:
 - run about too much
 - not be able to pay attention
 - act quickly without thinking about what will happen next (impulsive).
- It affects learning, making friends and how you think about yourself. It is not your fault.

While you are taking this medicine

- as well as taking this medicine you will also get help with ways to cope with your ADHD such as talking to ADHD specialists.
- this medicine should help you. But it does not cure ADHD.
- you will need to go to your doctor several times a year for check ups. This is to make sure the medicine is working and that you are growing and developing OK.
- if you take the medicine for more than one year, your doctor may stop your medicine to see if it is still needed. This will probably happen in a school holiday.
- do not drink alcohol. Alcohol may make the side effects of this medicine worse.
- if you are having sex, please talk to your doctor about contraception. Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies.

Some people cannot have this medicine

You cannot have this medicine if:

- you have a problem with your heart
- you feel very unhappy, depressed or have a mental illness.

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
- 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
- the medicine can also make you feel **sleepy**. If you feel sleepy, it is important **not to do outdoor sports** like riding a horse or bike, swimming or climbing trees. You could hurt yourself and others.
- your heart beating faster than usual.

If you feel unwell in any way while you are taking your medicine please tell an adult you trust straight away.

Other things to remember

- make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.
- 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.