



Package leaflet: Information for the patient
**Xenidate XL 18 mg
prolonged-release tablets**
methylphenidate hydrochloride

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.

- 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 or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's ones.
- If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xenidate XL is and what it is used for
2. What you need to know before you or your child takes Xenidate XL
3. How to take Xenidate XL
4. Possible side effects
5. How to store Xenidate XL
6. Contents of the pack and other information

1. What Xenidate XL is and what it is used for

What Xenidate XL is used for

Xenidate XL **is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD):**

- it is used in children aged 6 years and over and in adults.
- it is used only after trying treatments which do not involve medicines. Such as counselling and behavioural therapy.

Xenidate XL is not for use as a treatment for ADHD in children under 6 years.

How it works

Xenidate XL improves the activity of certain parts of the brain which are underactive. 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 therapy
- educational therapy
- social therapy.

It is prescribed only by doctors who have experience in children, adolescents, or adults with behaviour problems. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood. Although there is no cure for ADHD, it can be managed using treatment programmes.

About ADHD

Children and adolescents with ADHD find it hard:

- to sit still, and
- to concentrate.

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

Many children and adolescents struggle to do these things. However, ADHD can cause problems with everyday life. Children and adolescents with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places.

Adults with ADHD often find it hard to concentrate.

They often feel restless, impatient, and inattentive. They may have difficulty organising their private life and work.

Not all patients with ADHD need to be treated with medicine.

ADHD does not affect intelligence.

2. What you need to know before you or your child take methylphenidate

Do not take methylphenidate if you or your child:

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- have a thyroid problem
- have increased pressure in the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- have an eating problem when you or your child do not feel hungry or want to eat - such as 'anorexia nervosa'
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- 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
- have or 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)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor)- see 'Other medicines and Xenidate XL'
- have or have had 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:
 - feeling like killing yourself
 - severe depression, where you feel very sad, worthless and hopeless
 - mania, where you feel unusually excitable, over-active, and uninhibited.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Xenidate XL if you or your child:

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

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 applies to you or your child, before starting treatment. This is because methylphenidate can make these

problems worse. Your doctor will want to monitor how the medicine affects you or your child.

Checks that your doctor will make before you or your child start taking methylphenidate

These checks are to decide if methylphenidate is the correct medicine for you or your child. Your doctor will talk to you about:

- any other medicines you or your child are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you, your child or your family may have
- how you or your child are feeling, such as feeling high or low, having strange thoughts or if you or your child 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 your child or other family members have or have ever had. Your doctor will discuss whether you or your child are at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). Your doctor will check your or your child's mental health history, and check if any of your family has 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 or your child. Your doctor may decide that other medical tests are needed before you or your child start taking this medicine.

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful. For adult patients that are new to Xenidate XL, your doctor may refer you to a heart specialist.



Other medicines and Xenidate XL

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

Do not take methylphenidate if you or your child:

- 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 or your child's blood pressure (see 'Do not take Xenidate XL').

Tell your doctor or pharmacist if you are taking any of the following medicines for depression or anxiety:

- tricyclic antidepressant
- selective serotonin reuptake inhibitor (SSRI)
- serotonin and norepinephrine reuptake inhibitor (SNRI).

Taking methylphenidate with these type of medicine could cause a life threatening increase of 'serotonin' in the brain (serotonin syndrome), which may lead to feeling confused or restless, sweating, shivering, muscle jerks or fast heartbeat. If you develop these side effects, see a doctor straight away. If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you or your child 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 Parkinson's disease (such as levodopa)
- 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 or your child are taking are included in the list above, ask your doctor or pharmacist for advice before taking methylphenidate.

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

Having an operation

Tell your doctor if you or your child are going to have an operation. Methylphenidate should not be taken on the day of 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/anti-doping testing

This medicine may give a positive result when testing for drug use.

This includes testing used in sport.

Xenidate 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. Available data do not suggest an increased risk of overall birth defects, whilst a small increase in the risk of malformations of the heart when used during the first three months of pregnancy could not be ruled out. Your doctor will be able to give you more information about this risk.

Tell your doctor or pharmacist before using methylphenidate if you or your daughter:

- are having sex. Your doctor will discuss contraception
- are pregnant or think might be pregnant. Your doctor will decide whether methylphenidate should be taken
- are 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 or your daughter should breast-feed while taking methylphenidate.

Driving and using machines

You may feel dizzy, have problems focusing 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. There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>.

Xenidate XL contains sucrose and sodium

If you or your child have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Xenidate XL

How much to take

You or your child should always take this medicine exactly as your doctor or pharmacist 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 the daily dose by 18 mg, no sooner than once a week, if necessary. The aim should be the lowest dose that is effective for you. Your doctor will decide the maximum daily dose for you or your child.

- you or your child should take Xenidate XL once each day in the morning with a glass of water. **The tablet (or half tablet) must be swallowed whole and not chewed, broken or crushed.** The tablet may be taken with or without food.

Use in children 6 years and over:

- the recommended starting dose of Xenidate 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.

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Superseded Supplier Code	ART-1346-02						
Packing Site/Printer	Konapharm AG (Pratteln - CH)						
Sign-offs							

V3 MAY 2023

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