reading direction

Package leaflet: Information for the patient

Xenidate XL 36 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. For adult patients that are new to Xenidate XL, your doctor may refer you to a heart specialist. 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.

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 methylphenidate')

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 can be divided into equal doses. **The tablet (or half tablet) must not be chewed 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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Description	Methylphenidate Hydrochloride 36 mg 30			Date: 11 MAY 2024		Time: 05:58	
Component Type	Leaflet	Site Barcode/ DataMatrix	4422	No. of colours	1	Page Count	1/2
Affiliate Item Code	ART-1352-03	Viatris SAP No.	400522495	Colours	Black		
Superseded Affiliate Item Code	ART-1352-02	Vendor Job No.	801273	Non-Print Colours	Keyline		
TrackWise/GLAMS Job No.	ART-1352-03	Artwork Proof No.	3				
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Supplier SAP No.	NA	Barcode Info	NA				
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Sign-offs							
							V3 MAY 2023

Use in adults

For adults who have taken Xenidate XL before:
- if you have already taken Xenidate 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 Xenidate XL before:
- the recommended starting dose is 18 mg daily.
- the maximum daily dose in adults is 72 mg.

If you or your child do not feel better after 1 month of treatment

If you or your child do not feel better, after 1 month of treatment, tell your doctor. You doctor may decide a different treatment is needed.

Things your doctor will do when you or your child is on treatment

Your doctor will carry out some tests:
- before you or your child starts - to make sure that Xenidate XL is safe and will be of benefit.
- after you or your child starts - 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 appetite
  * measuring height and weight
  * measuring blood pressure and heart rate
  * checking problems with mood, state of mind or any other unusual feelings. Or if these have got worse while taking Xenidate XL.

Long-term treatment

Xenidate XL does not need to be taken forever. If you or your child take Xenidate 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.

Not using Xenidate XL properly

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

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

If you or your child take more Xenidate XL than you or your child should

If you or your child have taken 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 or your child forget to take Xenidate XL

Do not take a double dose to make up for a forgotten dose. If you or your child have forgotten a dose, wait until the next dose.

If you or your child stop taking Xenidate XL

If you or your child 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 Xenidate XL.

If you have any further questions on the use of this medicine, 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 or your child 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 uninhibited (mania).

Very rare (may affect up to 1 in 10,000 people):
- heart attack
- sudden death
- suicidal attempt
- fits (epileptic 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 cannot be controlled 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)
- prolonged erections, sometimes painful, or an increased number of erections.

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 painful 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.
- 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, confusion
- trouble seeing or double vision
- swelling of the breasts in men
- 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 convulsion')
- 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 or your child's height and weight, as well as how well you or your child are eating.
- if you or your child are not growing as expected, then 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 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 Xenidate 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 bottle label and the carton box after 'EXP'. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions. However, the prolonged-release tablets should be stored in the original, child-resistant container.

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 protect the environment.

6. Contents of the pack and other information

What Xenidate XL contains:
- The active substance is methylphenidate hydrochloride. Each prolonged-release tablet contains 36 mg methylphenidate hydrochloride equivalent to 31.13 mg methylphenidate.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose (see section 2, Xenidate XL contains sucrose'), maize starch), hypromellose, talc, ethylcellulose, hydroxypropylcellulose, triethyl citrate, hypromellose acetate succinate, carmellose sodium, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, hydrochloric acid (pH adjustment).

Tablet coating: Titanium dioxide (E171), polyvinyl alcohol, macrogol (3350), talc, hydrochloric acid (pH adjustment).

What Xenidate XL looks like and contents of the pack

Xenidate XL 36 mg prolonged-release tablets are white to off-white, oblong, biconvex tablets of 11.3 x 5.3 mm with break scores on both sides. The tablet can be divided into equal doses.

The prolonged-release tablets are available in bottles with child-resistant screw caps.

Pack sizes:

28 or 30 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Mylan
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TrackWise/GLAMS Job No.	ART-1352-03	Artwork Proof No.	3		
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