

## Package leaflet: information for the user

## Metidate XL 27 mg Prolonged-Release Tablets

methylphenidate hydrochloride

ROWEX®

Read all of this leaflet carefully before you 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 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.

## What is in this leaflet

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

## 1 What Metidate XL is and what it is used for

## What it is used for

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

- It is used in children, 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.
- Methylphenidate is not for use as a treatment for ADHD in children under 6 years of age or in adults. When treatment was started at a younger age, it might be appropriate to continue taking Metidate XL when you become an adult. Your doctor will advise you about this.

## How it works

Methylphenidate 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
- 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 Metidate XL

## Do not take Metidate XL if you

- 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 your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- have an eating problem when you 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 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 taking medicines known as monoamine oxidase inhibitors (MAOIs) for depression, or have taken MAOIs in the last 14 days
- 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, overactive, and uninhibited

Do not take methylphenidate if any of the above applies 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 or pharmacist before taking Metidate XL if you are/have:

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

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 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. Your doctor may decide that other medical tests are needed before you start taking this medicine.

## Other medicines and Metidate XL

Tell your doctor or pharmacist 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.

## 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.

## Metidate XL and 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 and breast-feeding

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.
- pregnant or 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 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.

## Metidate XL contains lactose

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

## 3 How to take Metidate 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 Metidate XL once each day in the morning with a glass of water. The tablet may be taken with or without food.
- The tablet should be swallowed whole and not chewed, broken, or crushed. A small round hole is visible on one side of the tablet. It is needed for the intended release of Methylphenidate from the tablet. Besides this, do not take the tablet if it appears damaged.
- 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.

In some patients Metidate XL may cause sleeplessness. To avoid difficulty in falling asleep, it should not be taken too late in the morning unless the doctor recommends otherwise.

## 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 Metidate XL properly

If Metidate 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 Metidate 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.

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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
- dry nose and mouth

#### If you forget to take Metidate 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 Metidate 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 Metidate XL.

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

##### Your doctor will do some tests

- before you start to make sure that Metidate XL are 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:
  - o checking appetite
  - o measuring height and weight
  - o measuring blood pressure and heart rate
  - o checking problems with mood, state of mind or any other unusual feelings

Or if these have got worse while taking Metidate XL.

##### Long-term treatment

Metidate XL Prolonged-Release Tablets do not need to be taken forever. If you take Metidate 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 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 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, overactive and uninhibited (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 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 up to 1 in 10 people)

- headache
- feeling nervous
- not being able to sleep

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

- joint pain
- accommodation disorder
- tension headache
- dry mouth, thirst
- trouble falling asleep
- high temperature (fever)
- 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, tense, jittery movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable

and abnormal behaviour

- upset stomach or indigestion, stomach pain, diarrhoea, indigestion, feeling sick, stomach discomfort and being sick

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

- blurred vision, dry eyes
- constipation
- chest discomfort
- blood in the urine
- listlessness
- shaking or trembling
- double vision or blurred vision
- 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, excessive awareness of surroundings, problems sleeping
- taking too much

**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
- inflammation or blocked arteries in the brain
- 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
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)

#### 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 Metidate 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 carton and label after EXP.

The expiry date refers to the last day of that month.

The shelf life after first opening of the bottle is 6 months. Unopened: this medicinal product does not require any special storage conditions.

After opening Store below 25°C.

The pack contains drying plug. This plug is 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 protect the environment.

## 6 Contents of the pack and other information

#### What Metidate XL 27 mg Prolonged-Release Tablets contains

The active substance is methylphenidate hydrochloride. Each tablet contains 27 mg of methylphenidate hydrochloride.

The other ingredients are:

- **drug layer:** polyethylene oxide, succinic acid, povidone (K 25), butylhydroxytoluene, stearic acid
- **push layer:** polyethylene oxide, sodium chloride, povidone (K 25), butylhydroxytoluene, iron oxide red (E 172), stearic acid
- **membrane layer:** cellulose acetate, poloxamer 188
- **drug coat:** hypromellose, succinic acid
- **film coat:** film coating mixture: white (lactose monohydrate, hypromellose, titanium dioxide (E 171), macrogol 4000, iron oxide black (E 172))

#### What Metidate XL looks like and contents of the pack

##### Metidate XL 27 mg Prolonged-Release Tablets

Light grey, round film-coated tablet with a delivery orifice (visible round small hole) on one side.

The medicinal product is available in bottles containing 28, 30, 50, 56, 98, 100 or 120 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturers

##### Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

##### Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

#### This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Methylphenidate Hexal
Ireland	Metidate XL 27 mg Prolonged-Release Tablets

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