

Matoride® XL 18 mg Prolonged-Release Tablets

Matoride® XL 36 mg Prolonged-Release Tablets

Matoride® XL 54 mg Prolonged-Release Tablets

(methylphenidate hydrochloride)

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

This medicine is available using the above names but will be referred to as Matoride XL throughout this leaflet. It contains the active substance methylphenidate hydrochloride. The name methylphenidate will also be used in this leaflet.

What is in this leaflet

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

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

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

- It is used in children and adolescents aged between 6 years and 18.
- It is used only after trying treatments which do not involve medicines, such as counselling and behavioural therapy.

Matoride 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 Matoride XL when your child becomes an adult. Your doctor will advise your child about this.

How it works

Matoride 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 and adolescents with behaviour problems. 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
- hard 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.

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

ADHD does not affect the intelligence.

2. What you need to know before your child takes Matoride XL Do not take Matoride XL if your child

- is allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6).
- has a thyroid problem
- has increased pressure in the eye (glaucoma)
- has a tumour of the adrenal gland (phaeochromocytoma)
- has an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
- has very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- has ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or was born with a heart problem
- has had a problem with the blood vessels in the 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)
- is currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) see - "Other medicines and Matoride XL".
- has 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, overactive and uninhibited

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

Warnings and precautions

Talk to your doctor before taking Matoride XL if your child:

- has liver or kidney problems
- has problems with swallowing or swallowing whole tablets
- has a narrowing or blockage of the gut or food-pipe
- has had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- has ever abused or been dependent on alcohol, prescription medicines or street drugs
- is a girl and has started having periods (see the 'Pregnancy and breast-feeding' section below)
- has hard-to-control, repeated twitching of any parts of the body or repeats sounds and words
- has high blood pressure
- has a heart problem which is not in the 'Do not take' section above
- has 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')
 - feeling aggressive or hostile
 - 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 your child before starting treatment. This is because Matoride XL can make these problems worse. Your doctor will want to monitor how the medicine affects your child.

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.

Checks that your doctor will make before your child starts taking Matoride XL

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

- any other medicines your child is 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 your child is feeling, such as feeling high or low, having strange thoughts or if your child has 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 your child or other family members have ever had.

Your doctor will discuss whether your child is at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check yours or your child's 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 your child. Your doctor may decide that other medical tests are needed before your child starts taking this medicine.

Other medicines and Matoride XL

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

Do not take methylphenidate if your child:

- is taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or has taken an MAOI in the last 14 days

Taking an MAOI with methylphenidate may cause a sudden increase in blood pressure (see "Do not take Matoride XL").

Tell your doctor or pharmacist if your child is 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 types 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 your child develops these side effects, see a doctor straight away.
- 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 your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking methylphenidate.

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

Having an operation

Tell your doctor if your child is 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 and heart rate during the operation.

Drug testing

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

Matoride 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 and breast-feeding

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 your daughter is:

- having sex. Your doctor will discuss contraception
- pregnant or think might be pregnant.

Your doctor will decide whether methylphenidate should be taken.
- breast-feeding or planning to breast-feed.

Methylphenidate passes into breast milk. Therefore, your doctor will decide whether your daughter should breast-feed while taking methylphenidate.

Driving and using machines

Your child 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 as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Matoride XL contains lactose and sodium

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

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

3. How to take Matoride XL

How much to take

Your child should 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 the daily dose by 18mg no sooner than once a week if necessary.
- The aim should be the lowest dose that is effective for your child. Your doctor will decide the maximum daily dose for your child.
- Your child should take Matoride 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 active substance has been released and sometimes the tablet shell may appear in the stools. This is normal.

Use in children aged 6 years and over

- the recommended starting dose of Matoride 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.

If your child does not feel better after 1 month of treatment

If your child does not feel better after 1 month of treatment tell your doctor. Your doctor may decide that your child needs a different treatment.

Not using Matoride XL properly

If Matoride XL is not used properly, this may cause abnormal behaviour. It may also mean that your child starts to depend on the medicine. Tell your doctor if your child has ever abused or been dependent on alcohol, prescription medicines or street drugs. This medicine is only for your child. Do not give this medicine to anyone else, even if their symptoms seem similar.

If your child takes more Matoride XL than you should

If your child takes 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,
- dry nose and mouth.

If your child forgets to take Matoride XL

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

If your child stops taking Matoride XL

If your child suddenly stops taking this medicine, 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 Matoride XL.

Things your doctor will do when your child is on treatment Your doctor will do some tests

- before your child starts - to make sure that Matoride XL is safe and will be of benefit
- after 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 Matoride XL.

• Long-term treatment

Matoride XL does not need to be taken forever. If your child takes Matoride 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 your child has 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 medicines 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 your child has 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.
- nausea
- dry mouth

Common (may affect up to 1 in 10 people)

- joint pain
- blurred vision
- tension headache
- 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
- 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, 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

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, 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)
- 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 child's height and weight, as well as how well your child is eating.
- If your child is 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website:

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 Matoride 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 carton and label after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions before first opening the bottle. After opening, do not store 25°C. The tablets can be stored for 6 months in the bottle after the first opening. The pack contains drying plug. This plug is used to keep the tablets dry and should not be eaten.
- If your tablets become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Matoride XL contains

The active substance is methylphenidate hydrochloride

- Each prolonged-release tablet contains 18 mg of methylphenidate hydrochloride.
- Each prolonged-release tablet contains 36 mg of methylphenidate hydrochloride.
- Each prolonged-release tablet contains 54 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, red iron oxide (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

In addition in 18 mg prolonged release tablets: yellow iron oxide (E 172)

In addition in 54 mg prolonged release tablets: red iron oxide (E 172), yellow iron oxide (E 172).

What Matoride XL looks like and contents of the pack

[18 mg] - Light yellow film-coated tablet of round shape (diameter 8mm) with a delivery orifice (visible small round hole) on one side.

[36 mg] - White film-coated tablet of round shape (diameter 10mm) with a delivery orifice (visible small round hole) on one side.

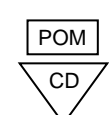
[54 mg] - Red film-coated tablet of round shape (diameter 10mm) with a delivery orifice (visible small round hole) on one side.

The medicine is available in plastic bottles containing 30 tablets.

Manufacturer and product licence holder

Manufactured by Lek Pharmaceuticals d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia.

Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharma Ltd.

	Matoride XL 18 mg Prolonged-Release Tablets PL 20636/2768
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