

Package Leaflet: Information for the user

Phenilzhar 18 mg prolonged release tablets

Phenilzhar 27 mg prolonged release tablets

Phenilzhar 36 mg prolonged release tablets

Phenilzhar 54 mg prolonged release tablets

methylphenidate hydrochloride

Read all of this leaflet carefully before you or your child start 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/your child's.
- 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 <invented name> is and what it is used for
2. What you need to know before you or your child take <invented name>
3. How to take <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <invented name> is and what it is used for

What it is used for

<invented name> 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.

<invented name> is not for use as a treatment for ADHD in children under 6 years of age.

How it works

<invented name> 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 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 the intelligence.

2. What you need to know before you or your child take <invented name>

Do not take <invented name> 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 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 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)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor)- see 'Other medicines and < invented name>'
- 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:
 - feeling like killing yourself
 - severe depression, where you feel very sad, worthless and hopeless
 - mania, where you feel unusually excitable, over-active, and un-inhibited.

Do not take methylphenidate if any of the above apply 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 before taking < invented name> 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 (EEGs)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs

- are female and have started having periods (see the ‘Pregnancy and breast-feeding section below)
- have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- have high blood pressure
- have a heart problem which is not in the ‘Do not take <invented name> if you or your child’ section above
- have a mental health problem which is not in the ‘Do not take <invented name> if you or your child’ 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 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.

If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of <invented name>.

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 you or your child start taking <invented name>

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 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 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’). 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 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 <invented name>, your doctor may refer you to a heart specialist.

Other medicines and <invented name>

Tell your doctor 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 blood pressure (see “Do not take <invented name> if you or your child”).

Tell your doctor or pharmacist if you or your child 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 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 you or your child 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:

- 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

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

<invented name> 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 you or your daughter are:

- having sex. Your doctor will discuss contraception with you

- pregnant or think you 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 you or your daughter should breast-feed while taking methylphenidate.

Driving and using machines

You or 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.

<invented name> contains lactose

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

<invented name> contains sodium

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

3. How to take <invented name>

How much to take

You or 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 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 <invented name> once each day in the morning with a glass of water.

The tablet should be swallowed whole and not chewed, broken, or crushed since it may affect how the medicine works in the body. The tablet may be taken with or without food.

The tablet does not dissolve completely after all of the medicine 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 <invented name> 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

Use in adults

- the maximum daily dose in adults is 72 mg.

For adults who have taken <invented name> before:

- if you have already taken <invented name> 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 <invented name> before:

- the recommended starting dose is 18 mg daily.

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. Your doctor may decide that you or your child need a different treatment.

Not using <invented name> properly

If < invented name> 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 <invented name> than you should

If you or your child take 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 heartbeat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you or your child forget to take <invented name>

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

If you or your child stop taking <invented name>

If you or your child suddenly stop 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 <invented name>.

Things your doctor will do when you or your child are on treatment:**Your doctor will do some tests**

- before you or your child start - to make sure that <invented name> is safe and will be of benefit.
- after you or your child 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 problems with your mood, state of mind or any other unusual feelings. Or if these have got worse while taking < invented name>.

Long-term treatment

<invented name> does not need to be taken for ever. If you or your child take <invented name> 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 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 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 medicine 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 you or your child 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 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 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 eye
- 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.
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

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
- cold feeling in the arms and legs
- 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
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)
- 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 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 national reporting system listed in Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

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.

This medicine does not require any special temperature storage conditions

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 <invented name> contains

The active substance is methylphenidate hydrochloride

- Each tablet contains 18 mg, 27 mg, 36 mg or 54 mg of methylphenidate hydrochloride.

The other ingredients are:

- *Tablet core*: hypromellose, macrogol, succinic acid, magnesium stearate, sodium chloride, silica colloidal anhydrous, black iron oxide (E172).
- *Film coating*: cellulose acetate, macrogol.
- *Clear coating*: hypromellose, macrogol, phosphoric acid (for pH adjustments).
- *Colour coating*: lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), yellow iron oxide (E172) (18 mg), red iron oxide (E172) (18mg, 27mg, 54mg), black iron oxide (E172) (27mg).

What <invented name> looks like and contents of the pack

- 18 mg: Round, biconvex, yellow film-coated tablets of approximately 9 mm of diameter with a small hole in one side of the tablet.
- 27 mg: Round, biconvex, grey film-coated tablets of approximately 9 mm of diameter with a small hole in one side of the tablet.
- 36 mg: Round, biconvex, white film-coated tablets of approximately 10 mm of diameter with a small hole in one side of the tablet.
- 54 mg: Round, biconvex, pink film-coated tablets of approximately 10 mm of diameter with a small hole in one side of the tablet

The medicine is available in a plastic bottle, including 2 desiccant canisters, with plastic child resistant cap. The desiccant canisters are used to keep the tablets dry and should not be eaten.

Pack sizes are: 28 tablets; 30 tablets; 60 tablets (2x30) and 90 tablets (3x30).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

This medicine is authorised in the Member States of the EEA under the following names:

Sweden: Phenilzhar 18 mg; 27 mg, 36 mg, 54 mg depottablett

France: Methylphenidate LP Biogaran 18 mg, 36 mg, 54 mg comprimé à libération prolongée

Austria: Conmethyl 18 mg, 27 mg, 36 mg, 54 mg-Retardtabletten

Czechia: Medate

Estonia: Metab

Lithuania: Metab 18 mg, 27 mg, 36 mg, 54 mg pailginto atpalaidavimo tabletės

Romania: <To be completed nationally>

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