

PACKAGE LEAFLET: INFORMATION FOR THE USER

MEDIKINET® MR 5 mg modified-release capsules, hard
MEDIKINET® MR 10 mg modified-release capsules, hard
MEDIKINET® MR 20 mg modified-release capsules, hard
MEDIKINET® MR 30 mg modified-release capsules, hard
MEDIKINET® MR 40 mg modified-release capsules, hard

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. Do not pass it on to others. It may harm them, even if their symptoms 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 MEDIKINET MR is and what it is used for
- 2 What you need to know before you or your child takes MEDIKINET MR
- 3 How to take MEDIKINET MR
- 4 Possible side effects
- 5 How to store MEDIKINET MR
- 6 Contents of the pack and other information

1 WHAT MEDIKINET MR IS AND WHAT IT IS USED FOR

What it is used for

MEDIKINET MR is used to treat 'attention deficit hyperactivity disorder' (ADHD).

- It is used in children and 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.

MEDIKINET MR is not for use as a treatment for ADHD in children under 6 years of age or in adults. If you have been successfully treated with MEDIKINET MR as an adolescent for ADHD, if your symptoms persist into adulthood and a need for further therapy has been determined, it might be appropriate to continue taking MEDIKINET MR when you become an adult. Your doctor will advise you about this.

How it works

MEDIKINET MR 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.

MEDIKINET MR treatment must only be initiated by, and used under the supervision of, a specialist in childhood and/or adolescent behavioural disorders. 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 OR YOUR CHILD TAKES MEDIKINET MR

Do **not** take MEDIKINET MR

If you or 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 MEDIKINET MR'
- 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:
 - o feeling like killing yourself
 - o severe depression, where you feel very sad, worthless and hopeless
 - o mania, where you feel unusually excitable, over-active, and un-inhibited.
- has a history of pronounced lack of gastric acid (anacidity of the stomach) with a pH value above 5.5
- is taking medicines to reduce secretion of gastric acid or to treat excessive acidity of the stomach (H₂ receptor blocker or antacid treatment).

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 takes methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

Talk to your doctor before taking MEDIKINET MR if you or 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 female 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')
 - starting to be aggressive or hostile, or 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 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 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 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 you or your child is feeling, such as feeling high or low, having strange thoughts or if you or 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 you or your child or other family members have ever had. Your doctor will discuss whether you or your child is at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check you 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.

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.

Drug testing

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

Athletes must be aware that this medicinal product may cause a positive reaction to 'anti-doping' tests.

Other medicines and MEDIKINET MR

Please tell your doctor or pharmacist if you or your child is taking, has recently taken or may take any other medicines.

Do not take methylphenidate if you or 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.

If you or your child is taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you or your child is 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.

MEDIKINET MR must not be taken together with H₂ receptor blockers or antacids which are used to reduce gastric acid secretion or to counteract excessive acidity in the stomach, as this could lead to a faster release of the total amount of active substance.

If you are in any doubt about whether any medicines you or your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking methylphenidate.

Having an operation

Tell your doctor if you or 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 during the operation.

Taking methylphenidate 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

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:

- is having sex. Your doctor will discuss contraception.
- is pregnant or think might be pregnant. Your doctor will decide whether methylphenidate should be taken.
- is 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 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.

MEDIKINET MR contains sucrose

If you or your child has 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 capsule, that is to say essentially 'sodium-free'.

3 HOW TO TAKE MEDIKINET MR

How much to take

You or your child should always take MEDIKINET MR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

In children and adolescents, the maximum daily dose is 60 mg.

When used for the continuation of treatment from adolescence into adulthood, the daily dose is 1 mg per kg body weight, up to a maximum of 80 mg per day.

- Your doctor will usually start treatment with a low dose and increase it gradually as required.
- Your doctor will tell you what strength of capsule to take each day.
- Do not split the dose of a capsule; take the entire contents of the capsule.
- MEDIKINET MR should not be taken too late in the morning as it may cause disturbances in sleep.

Your doctor will do some tests

- before you or your child starts - to make sure that MEDIKINET MR 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 MEDIKINET MR.

How to take

The medicinal product is intended for oral use.

Take MEDIKINET MR in the morning **with or after** breakfast. This is very important in order to obtain sufficiently prolonged action. The capsules may be swallowed whole with a drink of water.

Alternatively, you can open the capsules, sprinkle the capsule contents onto a small amount (teaspoon) of applesauce or yoghurt and take it immediately. In this case food should be eaten as well, of course. Do not store for future use.

The capsules and the capsule contents must not be crushed or chewed.

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

If you or your child does not feel better, tell your doctor. They may decide a different treatment is needed.

Long-term treatment

MEDIKINET MR does not need to be taken for ever. If you or your child takes MEDIKINET MR for more than a year, your doctor should stop treatment for a short time, for children, this may happen during a school holiday. This will show if the medicine is still needed.

Not using MEDIKINET MR properly

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

If you or your child takes more MEDIKINET MR than you should

If you or your child takes too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken.

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 forgets to take MEDIKINET MR

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

If you or your child stops taking MEDIKINET MR

If you or 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 MEDIKINET MR.

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, but 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 swings¹ 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
- fits (seizures, convulsions, epilepsy)
- skin peeling or purplish red patches
- 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
- paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your 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 easily¹
- 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.

>>> please turn over

Not known: frequency cannot be estimated from available data

- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems).

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 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
- dry mouth
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite or decreased appetite
- panic attack
- toothache
- itching, rash or raised red itchy rashes (hives)
- cough, sore throat or nose and throat irritation
- high blood pressure, fast heart beat (tachycardia)
- feeling dizzy, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, stressed, irritable and abnormal behaviour
- stomach pain, diarrhoea, feeling sick, stomach discomfort, indigestion, thirst and being sick
- excessive teeth grinding (bruxism)
- excessive sweating³.

Uncommon: may affect up to 1 in 100 people

- constipation
- inflammation of the mucous membranes of stomach and small intestine
- chest discomfort
- blood in the urine
- shaking or trembling¹
- double vision or blurred vision
- muscle pain, muscle twitching, muscle tightness
- shortness of breath or chest pain
- increases in liver test results (seen in a blood test)
- anger, feeling restless¹ or tearful, excessive awareness of surroundings, problems sleeping[#], tension.

Rare: may affect up to 1 in 1,000 people

- changes in sex drive²
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men²
- redness of the skin, red raised skin rash.

Very rare: may affect up to 1 in 10,000 people

- heart attack
- sudden death
- 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
- suicidal attempt, abnormal thinking, lack of feeling or emotion¹, 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 available data

- migraine¹
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true, confusion
- severe stomach pain, often with feeling and being sick
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- dry skin
- erectile dysfunction
- prolonged erections, sometimes painful, or an increased number of erections
- excessive uncontrolled talking
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering.

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 you or your child's height and weight, as well as how well you or your child is eating.
- If you or your child is not growing as expected, then treatment with methylphenidate may be stopped for a short time.

¹ Frequency derived from data and experiences from children and adolescents but may be higher in adults due to results of clinical trials.

² Frequency derived from clinical trials in adult patients but may be also relevant for children and adolescents.

³ Side effects from clinical trials in adult patients that were reported with a higher frequency than in children and adolescents.

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5 HOW TO STORE MEDIKINET MR

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 blister and the box after "EXP". The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store in the original package in order to protect from moisture.

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 MEDIKINET MR contains:

The active substance is: methylphenidate hydrochloride

MEDIKINET MR 5 mg modified-release capsules, hard

Each modified-release capsule, hard contains 5 mg methylphenidate hydrochloride equivalent to 4.35 mg methylphenidate.

MEDIKINET MR 10 mg modified-release capsules, hard

Each modified-release capsule, hard contains 10 mg methylphenidate hydrochloride equivalent to 8.65 mg methylphenidate.

MEDIKINET MR 20 mg modified-release capsules, hard

Each modified-release capsule, hard contains 20 mg methylphenidate hydrochloride equivalent to 17.30 mg methylphenidate.

MEDIKINET MR 30 mg modified-release capsules, hard

Each modified-release capsule, hard contains 30 mg methylphenidate hydrochloride equivalent to 25.95 mg methylphenidate.

MEDIKINET MR 40 mg modified-release capsules, hard

Each modified-release capsule, hard contains 40 mg methylphenidate hydrochloride equivalent to 34.60 mg methylphenidate.

The other ingredients are:

Capsule content:

Sugar spheres (containing sucrose and maize starch), Methacrylic acid-ethylacrylate-copolymer (1:1), Talc, Triethyl citrate, Poly(vinyl alcohol), Macrogol 3350, Polysorbate 80, Sodium hydroxide, Sodium laurilsulfate, Simeicone, Silica colloidal anhydrous, Methylcellulose, Sorbic acid, Indigo carmine, aluminium lake (E 132)

Capsule shell:

Gelatin, Titanium dioxide (E 171), Sodium laurilsulfate, Purified water additional in the capsule shell of MEDIKINET MR 10 mg and 20 mg: Erythrosine (E 127), Patent blue V (E 131) additional in the capsule shell of MEDIKINET MR 30 mg and 40 mg: Erythrosine (E 127), Iron oxide black (E 172), Indigo carmine (E 132)

What MEDIKINET MR looks like and contents of the pack:

MEDIKINET MR 5 mg modified-release capsules, hard

White opaque capsule body/white opaque capsule cap (15.9 mm) containing white and blue pellets.

MEDIKINET MR 10 mg modified-release capsules, hard

White opaque capsule body/mauve opaque capsule cap (15.9 mm) containing white and blue pellets.

MEDIKINET MR 20 mg modified-release capsules, hard

Mauve opaque capsule body/mauve opaque capsule cap (15.9 mm) containing white and blue pellets.

MEDIKINET MR 30 mg modified-release capsules, hard

Light grey opaque capsule body/dark violet opaque capsule cap (15.9 mm) containing white and blue pellets.

MEDIKINET MR 40 mg modified-release capsules, hard

Grey opaque capsule body/dark violet opaque capsule cap (18.0 mm) containing white and blue pellets.

Pack sizes:

Boxes containing 28 or 30 modified-release capsules, hard packed in blisters made of PVC/PVdC aluminium foil.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG

Kuhloweg 37, 58638 Iserlohn

Germany

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

Germany	Medikinet retard 5 mg, 10 mg, 20 mg, 30 mg, 40 mg Hartkapseln mit veränderter Wirkstofffreisetzung
Belgium	Medikinet retard 5 mg, 10 mg, 20 mg, 30 mg, 40 mg Capsule met gereguleerde afgifte, hard
Estonia	Medikinet XL 5 mg, 10 mg, 20 mg, 30 mg, 40 mg
France	Medikinet 5 mg, 10 mg, 20 mg, 30 mg, 40 mg Gélule à libération modifiée
Ireland	Medikinet MR 5 mg, 10 mg, 20 mg, 30 mg, 40 mg modified release capsules, hard
Italy	Medikinet 5 mg, 10 mg, 20 mg, 30 mg, 40 mg Capsula rigida a rilascio modificato
Latvia	Medikinet XL 5 mg, 10 mg, 20 mg, 30 mg, 40 mg ilgstošās darbības cietās kapsulas
Lithuania	Medikinet XL 5 mg, 10 mg, 20 mg, 30 mg, 40 mg modifikuoto atpalaidavimo kietos kapsulės
Portugal	Medikinet 5 mg, 10 mg, 20 mg, 30 mg, 40 mg Cápsula de libertação modificada

This leaflet was last revised in December 2020.