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Erstellt am:

Art.-Nr.:

Art.-Bez.:

Farben:

Größe (offen):

Größe (gefalzt):

Zeichnungsnummer:

Laetuscode-Nr.:

282 x 575 mm

Anmerkungen:

MEDICE

THE HEALTH FAMILY

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

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.

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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 aged 6 years and over and in adults.
- It is used only after treatments have been tried, which do not involve medication e.g. counselling and behavioural therapy and which have been insufficient.

MEDIKINET MR is not for use as a treatment for ADHD in children under 6 years of age.

How it works

MEDIKINET MR improves the activity of certain parts of the brain, which are under-active. The medicine can help improve attention span and 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 doctor, specialised in the treatment of ADHD, such as an expert paediatrician, a child and adolescent psychiatrist or a psychiatrist. A careful examination by this doctor is required. If you as an adult have not been treated before, the doctor will perform tests to confirm that you have been affected by ADHD since childhood. 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.

Patients can have ADHD in varying degrees with symptoms including:

- lack of concentration
- restlessness
- hyperactivity
- impulsivity
- emotional instability
- disorganised thinking

This is shown by, for example:

- difficulty concentrating
- forgetfulness
- talking too much
- difficulties in planning and carrying out tasks to completion
- “blindfold actions”
- impatience

ADHD does not affect the intelligence of a child or young person.

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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, proton pump inhibitor 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 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 (tics)
- 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. Methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or 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 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 and 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 behavioural 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. For adult patients that are new to Medikinet MR, your doctor may refer you to a heart specialist.

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. Tell your doctor if you or your child is taking medicines to treat:

- depression
- mental health problems
- epilepsy
- blood pressure problems
- cough and colds. Some remedies 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, proton pump inhibitors 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 she 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, feel drowsy, have problems focussing or have blurred vision, have hallucinations or other side effects in the central nervous system 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 dosage unit, that is to say essentially ‘sodium-free’.

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HOW TO TAKE MEDIKINET MR

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.

Dosage

Use in children

The maximum daily dose is 60 mg.

- 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.
- MEDIKINET MR should not be taken too late in the morning as it may cause disturbances in sleep.

Use in adults

For adults who have taken MEDIKINET MR before

- if you have already taken MEDIKINET MR 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
- the maximum daily dose is based among other things on your body weight (see below)

For adults who have not taken MEDIKINET MR before

The recommended starting dose is 10 mg daily.

- your doctor will increase your dose in increments of 10 mg daily, depending on how well you tolerate the medicine and how effective it is
- the aim should be the lowest dose that is effective for you
- the maximum daily dose is based among other things on your body weight (see below)
- your doctor will decide the maximum daily dose for you the daily dose is 1 mg per kg body weight, up to a maximum of 80 mg of methylphenidate daily

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

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 for children
 - measuring weight for adults
 - 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.

Method of Administration

The medicinal product is intended for oral use.

Children take MEDIKINET MR in the morning **with or after** breakfast.

Adults take MEDIKINET MR with or after breakfast **and** lunch.

MEDIKINET MR is a form of methylphenidate with “controlled release” action, which releases the drug gradually over a prolonged period of time. Taking the capsule with or after meals is very important for their action to be delayed. The capsules may be swallowed whole with a drink of water. Alternatively, you can open the capsules, sprinkle the contents onto a small amount (tablespoon) of applesauce or yoghurt and take it immediately. 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 after 1 month of treatment, tell your doctor. Your doctor may decide that you or your child needs a different treatment.

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 at least once per year for a short time. In case of 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. This medicine is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

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

If you or your child takes too much of the medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. You may need medical treatment.

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, muscle spasms, fever and reddish-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

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.

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