

# MEDIKINET MR<sup>®</sup> Hard Capsules

Methylphenidate Hydrochloride 5mg, 10mg, 20mg, 30mg & 40mg

## What is in this leaflet

1. What Medikinet MR is used for
2. How Medikinet MR works
3. Before you use Medikinet MR
4. How to use Medikinet MR
5. While you are using Medikinet MR
6. Side effects
7. Storage and disposal of Medikinet MR
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

### 1. What Medikinet MR is used for

Medikinet MR contains active substance *methylphenidate hydrochloride*. It is a mild stimulant acting on central nervous system (CNS).

Medikinet MR is used to treat *attention deficit hyperactivity disorder* (ADHD).

It is used in children and young people between the ages of 6 to 18 and in adults from the age of 18 years on.

It is used only after trying treatments which do not involve medicines. Such as counselling and behavioural therapy.

Medikinet MR is not for in treatment for ADHD in children under 6 years of age as safety and benefits are unknown.

### 2. How Medikinet MR 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 behavioural disorders. A very thorough assessment of the ailments is necessary. The accompanying treatment programmes can contribute to an improved management of the disorder.

### 3. Before you use Medikinet MR

#### When you must not use it

Do not take Medikinet MR if you or your child has the followings:

- Allergic (hypersensitive) to *methylphenidate* or any of the other ingredients of Medikinet MR (refer to section 'Other information').
- Thyroid problem
- Increased pressure in the eye (glaucoma)
- Tumour of the adrenal gland (*pheochromocytoma*)
- Has an eating problem where you or your child 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*)
- Currently taking or has taken within the last 14 days an antidepressant (known as a *monoamine oxidase inhibitor*) – see section 'Taking other medicines'
- Has mental health problems such as: a *psychopathic* or

*borderline personality problem*, abnormal thoughts or visions or an illness called schizophrenia, and signs of a severe mood problem. (feeling like killing yourself, severe depression, where you feel very sad, worthless and hopeless, mania, where you feel unusually excitable, over- active, and uninhibited)

- Has history of pronounced lack of gastric acid (an acidity of the stomach) with a pH value above 5.5
- Taking medicines to reduce secretion of gastric acid or to treat excessive acidity of the stomach (H<sub>2</sub> receptor blocker, proton pump inhibitor or antacid treatment).

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

Do not use Medikinet MR if your is child under 6 years old

Exercise caution when using Medikinet MR in patients with liver or kidney problems.

#### Before you start to use Medikinet MR

Before you take Medikinet MR you should tell your doctor or pharmacist if you or your child experienced the followings:

- Had taken or currently taking any medicines
- Had any family history of sudden unexplained death
- Any other medical problems (such as heart problems) you, your child or your family may have
- Having feeling such as high or low, and strange thoughts or if any of feelings or experienced in the past
- There is a family history of

# MEDIKINET MR<sup>®</sup> Hard Capsules

Methylphenidate Hydrochloride 5mg, 10mg, 20mg, 30mg & 40mg

- 'tics' (hard-to- control, repeated twitching of any parts of the body or repeating sounds and words)
- Had or having mental health or behavioural problems or other family members have ever had.

- Medicines that thin the blood to prevent blood clots
- H2 receptor blockers, proton pump inhibitors or any antacids

#### 4. How to take Medikinet MR

##### How much and when to use it

You or your child should always take Medikinet MR exactly as your doctor has told you. If you are not sure, kindly refer to your doctor or pharmacist.

- Your doctor will usually start treatment at low dose, which shall be taken with or after a meal, and increase it gradually as required.
- For children and adolescents, the maximum daily dose is 60 mg.
- For adults, the maximum daily dose is 1 mg *methylphenidate* per kg body weight, and a total daily dose of 80 mg *methylphenidate* should not be exceeded.
- *Immediate-release methylphenidate* tablet need to be taken in the morning and at noon due to the short duration of action. While for Medikinet MR it is a *modified- release form of methylphenidate hydrochloride* which releases the medicine gradually over a prolonged time period. It is recommended to be taken once daily in replacement of *immediate-release methylphenidate* tablet.

##### *Continuation of therapy with MEDIKINET MR*

If you or your child has benefited from treatment with MEDIKINET MR during childhood or adolescence, treatment may be continued at the same daily dose level (mg/day). It should regularly be checked, if an adjustment of the dose is necessary, depending on degree of efficacy and tolerability observed. In adult patients, a higher daily dose may be

required, as compared to children and adolescents. The lowest total daily dose that achieves satisfactory symptom control should be employed. The effect occurs within an hour after ingestion if the dose is sufficiently high.

##### *Initiation of treatment with MEDIKINET MR in adults*

The recommended starting daily dose is 10 mg. If necessary, your doctor will increase the daily dose by weekly increments of 10 mg, based on degree of efficacy and tolerability observed.

The lowest total daily dose that achieves satisfactory symptom control should be employed. The maximum daily dose shall be chosen according to your body weight. The medicinal product is intended for oral use.

Children and adolescents shall take one dose of MEDIKINET MR in the morning with or after breakfast to obtain a sufficiently prolonged action throughout the school day.

Children and adolescents shall not take their dose of MEDIKINET MR too late in the morning as it may cause disturbances in sleep.

Adults shall divide their total daily dose of MEDIKINET MR into two equal doses and shall take one dose in the morning and one at lunchtime, each with or after a meal to obtain a sufficiently prolonged action throughout the whole day.

The capsules may be swallowed whole with a drink of water. You can also open the capsules, sprinkle the capsule contents onto a small amount (tablespoon) 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.

##### How long to use it

MEDIKINET MR does not need to be taken forever. If you or your child takes MEDIKINET MR for more than a year, your doctor should stop treatment for a short time. For children and adolescents,

Your doctor will discuss whether you or your child is at risk of having mood swings (i.e. :'*bipolar disorder*'). Prior to initiating treatment with methylphenidate, assessment will be made based on you or your child's pre-existing psychiatric disorders/mental health history, and family history of suicide, bipolar disorder or depression. A family history thereof should be established.

You are encouraged to provide as much information to your doctor. Your doctor required the information to decide if Medikinet MR is suitable for you or your child. Your doctor may decide that other medical tests are needed before you or your child start taking this medicine.

##### If you are taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is important that you inform your doctor if you are already being treated with any of the followings:

- *Monoamine oxidase inhibitor (MAOI)*, a medicine used for depression, or has taken an MAOI in the last 14 days. Taking an MAOI with Medikinet MR may cause a sudden increase in blood pressure.
- Other medicines used for depression
- Medicines for severe mental health problems
- Medicines for epilepsy
- Medicines used to reduce or increase blood pressure
- Cough and cold remedies (some cough and cold remedies may contain medicines that can affect blood pressure)

# MEDIKINET MR<sup>®</sup> Hard Capsules

Methylphenidate Hydrochloride 5mg, 10mg, 20mg, 30mg & 40mg

this may happen during a school holiday. This will show if the medicine is still needed.

Tell your doctor if you or your child does not feel better after 1 month of treatment. Different treatment may be required.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## If you forget to take Medikinet MR

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

## If you take too much (overdose)

If you or your child takes too much of the medicine, contact your doctor or call an ambulance immediately. Inform doctor quantity of medicine that 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, dry nose and mouth, and muscle weakness and ache.

## 5. While you are using Medikinet MR

### Things you must and must not do

Take the medicine as directed by your doctor.

Avoid taking the medicine with alcohol. Alcohol may worsen side effects caused by Medikinet MR. Kindly take note that some food and medicines do contain alcohol. If you are not sure, kindly check with your doctor or pharmacist.

### Things to be careful of

### *Use of Long-Acting Methylphenidate Formulation*

Caution is advised if long-acting formulations are used interchangeably due to the differences between these formulations in frequency of dosing, administration with food and drug concentration achieved in blood.

### *Pregnancy and lactation*

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. Please inform your doctor or pharmacist if you or your child had the followings prior taking MEDIKINET MR :

- Had sexual intercourse. Your doctor may need to discuss on method of contraceptive.
- Pregnant or suspecting of pregnant. Your doctor will decide whether MEDIKINET MR is suitable to be taken.
- Breastfeeding or plan to breastfeed. MEDIKINET MR may be absorbed into the breastmilk. Doctor will need to decide if you or your child is suitable to breastfeed while on treatment with MEDIKINET MR.

### *Driving and handling of machine*

Methylphenidate improves attention. However, while on treatment with MEDIKINET MR, you or your child may feel dizzy, difficulty to concentrate, experienced blurred vision, hallucinations and nervous system side effects. If the followings happen, it is dangerous for you to drive or operate machine.

### *Important information on other ingredients in Medikinet MR*

MEDIKINET MR contains sucrose. If

you or your child has allergy to some sugars, kindly check with your doctor before taking this medicine.

## 6. Side effects

Like other medicines, Medikinet MR can cause side effects, although not everybody gets them.

Some side effects could be serious and if you or your child have any of the side effects as below, you should inform your doctor immediately. These side effects are based on data for children, adolescents and adults.

### Very common side effects (affects more than 1 in 10 people)

- Decreased appetite,
- Unable to sleep, feeling nervous,
- Headache
- Nausea, dry mouth

### Common side effects (affects less than 1 in 10 people)

- Cough, sore throat or nose and throat irritation,
- Loss of appetite
- Moderate reduction in weight and height gain (growth retardation) during prolonged use in children
- Abnormal behaviour,
- Feeling aggressive, agitated, anxious, depressed, stressed, restless, irritable
- Sleep disturbance
- Lack of interest with sex
- Panic attack
- Excessive teeth grinding (*bruxism*)
- Tremor
- Feeling unusually sleepy or drowsy, feeling dizzy
- Uncontrolled movements, being unusually active, inability to remain still
- Fast heartbeat (*tachycardia*), palpitations, uneven heartbeat (*arrhythmia*)
- High blood pressure
- Coldness in limbs
- Difficulty in breathing,
- Stomach pain/

# MEDIKINET MR<sup>®</sup> Hard Capsules

Methylphenidate Hydrochloride 5mg, 10mg, 20mg, 30mg & 40mg

- discomfort, diarrhea, stomach discomfort, indigestion, vomiting (usually occur at the beginning of treatment and may alleviate by concomitant food intake),
- Toothache
- Excessive sweating
- Unusual hair loss or thinning,
- Itching, rash or raised red itchy rashes (hives)
- Joint pain,
- High temperature (fever)
- Tiredness
- Thirsty
- Weight loss

## Uncommon side effects (affects less than 1 in 100 people)

- Inflammation of the mucous membranes of stomach and small intestines
- Signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, ear or other body parts, shortness of breath, wheezing or trouble breathing
- Exaggerated fear of danger or excessive awareness to surroundings
- Seeing, feeling or hearing unreal things
- Mood changes and swings, anger
- Thinking about or feeling like killing yourself
- A crying/almost crying state
- Uncontrolled speech and body movements (*Tourette's syndrome*)
- Mental disorders
- Tension
- Calmness/relaxation
- Inability to remain still
- Double or blurred vision
- Chest pain
- Constipation
- Increased liver enzymes
- Rapid blood flow through the Heart
- Muscle pain, twitching or Tightness
- Blood in the urine

## Rare side effects (affects less than 1 in 1,000 people)

- Changes in sex drive (*libido*)
- High energy and activity level
- Feeling disoriented
- Dilated pupils, vision problem
- Chest pain/discomfort
- Skin redness and skin rash
- Swelling of the breasts in men

## Very rare side effects (affects less than 1 in 10,000 people)

- Abnormally low level of white blood - cells / platelets/red blood cells
- Small, flat red spots under the skin (*thrombocytopenic purpura*)
- Thinking about killing yourself
- Short period depression
- Abnormal thoughts
- Lack of interest or concern
- Repetitive behaviour
- Excessive focus
- Involuntary body movement
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (*Raynaud's phenomenon*).
- A sudden increase in body temperature, very high blood pressure and severe convulsions (*Neuroleptic Malignant Syndrome*)
- Sudden death
- Heart attack
- Inflammation or blocked arteries in the brain
- Abnormal liver function and liver enzymes
- Redness and skin rash
- Muscle cramps and/or spasms

## Side effects with unknown frequency (cannot be estimated with available data)

- Abnormally low level of white blood cells, platelets, red blood cells
- False belief about situation, thought disturbances, confusion
- Rapid, uncontrollable, incoherent speech

- Abuse and dependence (more often with immediate-release methylphenidate formulations)
- Inflammation of blood vessels
- Bleeding in the brain
- seizures, migraine
- Tingling/pickling sensation on skin
- Trouble with speaking and/or understanding others' speech (*aphasia*)
- Stuttering when talking (*dysphemia*)
- Dry eye, Increased eye pressure
- Increased/ Decreased heartbeat, Chest discomfort
- Sudden warmth feeling/skin redness on upper body
- Cough and sore throat
- Nose bleed
- Nausea
- Spasm of the jaw muscles that makes it difficult to open the mouth (*trismus*)
- Inability to control the excretion of urine (*Incontinence*)
- Erectile dysfunction, Prolonged and increased erection
- Breast pain
- High fever
- Reduced ability to focus, lack of energy
- Influenza-like illness
- Thirsty
- Blood thyroid stimulating hormone increase
- Partner and family stress
- Ringing sound in ear (*tinnitus*)

## **Effects on growth**

When used for more than a year, Medikinet MR may cause reduced growth in some children. This affects less than 1 in 10 children.

If you or your child is not growing as expected, then treatment with Medikinet MR may be stopped for a short time.

If any of the side effects gets serious, or if you or your child experienced any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or

# MEDIKINET MR<sup>®</sup> Hard Capsules

Methylphenidate Hydrochloride 5mg, 10mg, 20mg, 30mg & 40mg

adverse drug reactions directly to the National Centre for Adverse Drug Reaction by visiting the website [www.npra.gov.my](http://www.npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## 7. Storage and disposal of Medikinet MR

Store below 30° C. Keep out of reach and sight of children. Do not use Medikinet MR after the expiry date which is stated on the blister and the box after EXP. Store in the original package in order to protect from moisture.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 8. Other information

### Product description

- **MEDIKINET MR 5 mg Hard Capsules:** White/opaque hard capsules size 3 with a black imprint containing white and blue pellets.
- **MEDIKINET MR 10 mg Hard Capsules:** Hard capsules size 3 with amethyst opaque cap and white opaque body with a black imprint containing white and blue pellets.
- **MEDIKINET MR 20 mg Hard Capsules:** Amethyst opaque hard capsules size 3 with a black imprint containing white and blue pellets.
- **MEDIKINET MR 30 mg Hard Capsules:** Hard capsules size 3 with a dark violet opaque cap with a white imprint and a light grey opaque body with a black imprint containing white and blue pellets
- **MEDIKINET MR 40 mg Hard Capsules:** Hard capsules size 2 with dark violet opaque cap with a white imprint and a grey opaque body with a black imprint containing white and blue pellets

### Ingredients

Active substance:

*methylphenidate hydrochloride*

- **MEDIKINET MR 5 mg Capsules:** Each capsule contains 5 mg *methylphenidate hydrochloride corresponding to 4.325mg methylphenidate*
- **MEDIKINET MR 10 mg Capsules:** Each capsule contains 10mg *methylphenidate hydrochloride corresponding to 8.65 mg methylphenidate*
- **MEDIKINET MR 20 mg Capsules:** Each capsule contains 20 mg *methylphenidate hydrochloride corresponding to 17.30 mg methylphenidate*
- **MEDIKINET MR 30 mg Capsules:** Each capsule contains 30 mg *methylphenidate hydrochloride corresponding to 25.95 mg methylphenidate*
- **MEDIKINET MR 40 mg Capsules:** Each capsule contains 40 mg *methylphenidate hydrochloride corresponding to 34.60mg methylphenidate*

### Other ingredients:

*In capsule content: Sugar sphere (sucrose, maize starch), methacrylic acid-ethylacrylate-copolymer (1:1) dispersion 30%, sodium laurilsulfate, polysorbate 80, talc, triethylcitrate, poly (vinyl alcohol), macrogol 3350, sodium hydroxide, simeticone emulsion 30%, silica colloidal anhydrous, methylcellulose, sorbic acid, indigo carmine, aluminium lake (E 132)*

*On capsule shell: gelatin, titanium dioxide (E 171)*

*Additional on the capsule shell of MEDIKINET MR 10 mg and 20mg: erythrosine (E 127), brilliant blue FCF (E 133)*

*Additional on the capsule shell of MEDIKINET MR 30 mg and 40mg:*

*erythrosine (E 127), brilliant blue FCF (E 133), black iron oxide (E 172)*

### MAL number:

**MAL18106136AZ**

**MAL18106134AZ**

**MAL18106133AZ**

**MAL18106137AZ**

**MAL18106139AZ**

### Manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG, Kuhlweg 37 D-58638 Iserlohn Germany

### Product registration holder

Hypkens Pharma Sdn Bhd C-L2-01, Block C, Axis Business Park, No.10 Jalan Bersatu 13/4, 46200 Petaling Jaya, Selangor, Malaysia

### Date of revision

July 2024

### Serial number

NPRA (R1/5) 15072024/150

# **MEDIKINET MR<sup>®</sup> Hard Capsules**

Methylphenidate Hydrochloride 5mg, 10mg, 20mg, 30mg & 40mg

---