

SCHEDULING STATUS

S6

**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  
**MEDIKINET MR 50 mg** modified-release capsules, hard  
**MEDIKINET MR 60 mg** modified-release capsules, hard

Methylphenidate hydrochloride

**Contains sugar:** 63.57 mg – 72.71 mg sucrose for **Medikinet MR 5 mg** modified-release capsules

**Contains sugar:** 127.14 mg – 145.42 mg sucrose for **Medikinet MR 10 mg** modified-release capsules

**Contains sugar:** 114.65 mg – 131.13 mg sucrose for **Medikinet MR 20 mg** modified-release capsules

**Contains sugar:** 69.60 mg – 79.61 mg sucrose for **Medikinet MR 30 mg** modified-release capsules

**Contains sugar:** 92.80 mg – 106.14 mg sucrose for **Medikinet MR 40 mg** modified-release capsules

**Contains sugar:** 116.00 mg - 132.68 mg sucrose for **Medikinet MR 50 mg** modified-release capsules

**Contains sugar:** 139.20 mg - 159.22 mg sucrose for **Medikinet MR 60 mg** modified-release capsules,

▼ 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 MEDIKINET MR 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 pharmacist, nurse or other healthcare provider.
- MEDIKINET MR has been prescribed for you or your child. Do not share your medicine with other people. 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

## WHAT MEDIKINET MR IS AND WHAT IT IS USED FOR

### What Medikinet MR is

**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.

**Medikinet MR 50 mg** modified-release capsules, hard

Each modified-release capsule, hard contains 50 mg methylphenidate hydrochloride, equivalent to 43.25 mg methylphenidate.

**Medikinet MR 60 mg** modified-release capsules, hard

Each modified-release capsule, hard contains 60 mg methylphenidate hydrochloride, equivalent to 51.90 mg methylphenidate.

Pharmacotherapeutic group: psychoanaleptics (A.1.2): psychostimulants, agents used for ADHD and nootropics; centrally acting sympathomimetics

### 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 who had ADHD onset in childhood.
- it is used only after other treatments which do not involve medication have been tried and have been insufficient, e. g. counselling and behavioural therapy.

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.

## **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 (H<sub>2</sub> receptor blocker, proton pump inhibitor or antacid treatment)
- if the patient is pregnant or breastfeeding their baby

Do not take MEDIKINET MR 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 MEDIKINET MR can make these problems worse.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium free’.

### **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. MEDIKINET MR 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 MEDIKINET MR**

These checks are to decide if MEDIKINET MR 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 MEDIKINET MR 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**

MEDIKINET MR 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 MEDIKINET MR 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 MEDIKINET MR may cause a sudden increase in blood pressure.

If you or your child is taking other medicines, MEDIKINET MR 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 H<sub>2</sub> 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 MEDIKINET MR.

### **Having an operation**

Tell your doctor if you or your child is going to have an operation. MEDIKINET MR 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 MEDIKINET MR 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**

MEDIKINET MR should not be taken during pregnancy or when breast-feeding. Tell your doctor or pharmacist

before using MEDIKINET MR if you or your daughter:

- is having sex. Your doctor will discuss contraception.
- is pregnant or think she might be pregnant.
- is breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk.

### **Driving and using machines**

You or your child may feel dizzy, have problems focussing or have blurred vision when taking MEDIKINET MR. If these happen, you should not drive, use machines, ride a bike or horse or climb trees.

### **MEDIKINET MR contains sucrose**

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

## **3. 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 in order 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, 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 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.

### **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.

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**

This medicine can cause side effects. 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:**

### **Frequent side effects**

- uneven heartbeat (palpitations)
- mood changes

### **Less frequent side effects**

- mood swings
- changes in personality
- seeing, feeling or hearing things that are not real- these are signs of psychosis
- uncontrolled speech and body movements (Tourette's) or worsening of it
- chest pain
- 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
- thinking about or feeling like killing yourself
- feeling unusually excited, over-active and un-inhibited (mania)
- 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), temporary lack of adequate blood and oxygen (ischemia) to the 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 easily
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome').

**Not known: frequency cannot be estimated from available data**

- unwanted thoughts that keep coming back
- unexplained fainting, 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:**

**Frequent side effects**

- headache
- feeling nervous
- not being able to sleep
- decreased appetite
- feeling agitated,
- feeling depressed or lack of feeling or emotion or showing much interest
- dry mouth
- feeling sick
- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- panic attack
- tooth ache
- itching, rash or raised red itchy rashes (hives),
- cough, sore throat or nose and throat irritation
- high blood pressure or other changes of blood pressure,
- fast heart beat (tachycardia) or irregular heart beat (arrhythmia)
- feeling dizzy,
- movements which you cannot control,

- being unusually active
- feeling aggressive, emotional unstable, anxious, stressed, irritable,
- behaving abnormally
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst, vomiting
- lack of appetite/not willing to eat
- weight loss
- excessive teeth grinding (bruxism)
- excessive sweating

### **Less Frequent side effects**

- shaking or trembling
- blurred vision
- muscle pain
- constipation
- inflammation of the mucous membranes of stomach and small intestine
- extra sound during heart beat (based on investigation findings)
- blood in the urine
- double vision
- muscle twitching
- muscle tightness
- shortness of breath or chest pain
- increases in liver test results (seen in a blood test)
- anger,
- feeling tearful
- feeling restless,
- excessive awareness of surroundings,
- feeling very calm or sleepy
- problems with the sleep in general
- fatigue
- tension
- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men
- redness of the skin, red raised skin rash
- pain resulting from not enough blood flow to the heart
- problems/changes in the menses
- 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,
- doing things over and over again,
- being obsessed with one thing,
- lack of energy,
- feeling sad over a short period of time
- fingers and toes feeling numb and cold, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon')

**Not known: frequency cannot be estimated from available data**

- migraine
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true,
- confusion,
- sad/dark thoughts
- feeling a bodily need of the medication or feeling its absence
- 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
- tension
- grind your teeth during sleep
- ADHD symptoms may come back or unwanted effects such as depression may appear after stop of medication
- tingling sensation
- problems with language and speaking
- retching
- disturbance in attention
- influenza like illness
- loss of energy / feeling weak
- feeling thirsty
- increases in blood thyroid stimulating hormone levels
- pain in the area of mouth and throat
- nose bleeding
- heart discomfort
- dry eye
- higher pressure inside the eye than normal
- stress with partner / family
- breast pain
- hot flush / flushing
- ringing in the ears (tinnitus)
- abuse
- pancytopenia (abnormal decrease in the levels of all type of blood cells)
- 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, MEDIKINET MR may cause reduced growth in some children.

- There may be lack of weight gain or height.
- Your doctor will carefully watch you or your child's height and weight, and how well you or your child is eating.
- If you or your child is not growing as expected, then treatment with MEDIKINET MR may be stopped.

## Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked

to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via [pv@mcpharma.co.za](mailto:pv@mcpharma.co.za).

## 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.

Store at or below 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.

**MEDIKINET MR 50 mg modified-release capsules, hard**

Each modified-release capsule, hard contains 50 mg methylphenidate hydrochloride equivalent to 43.25 mg methylphenidate.

**MEDIKINET MR 60 mg modified-release capsules, hard**

Each modified-release capsule, hard contains 60 mg methylphenidate hydrochloride equivalent to 51.90 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, Simeticone, 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 /- 20 mg:

Erythrosine (E 127), Patent blue V (E 131)

additional in the capsule shell of MEDIKINET MR 30 mg /- 40 mg /- 50 mg /- 60 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.

**MEDIKINET MR 50 mg modified-release capsules, hard**

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

**MEDIKINET MR 60 mg modified-release capsules, hard**

Dark violet opaque capsule body/dark violet opaque capsule cap (19.4 mm) containing white and blue pellets.

Pack sizes:

**MEDIKINET MR 5 mg** modified-release capsules, hard

Boxes containing 20, 30 or 50 modified-release capsules, hard packed in blisters made of PVC/PVdC aluminium foil.

**MEDIKINET MR 10 mg /- 20 mg /- 30 mg /- 40 mg** modified-release capsules, hard

Boxes containing 20, 28, 30 or 50 modified-release capsules, hard packed in blisters made of PVC/PVdC aluminium foil.

**MEDIKINET MR 50 mg /- 60 mg** modified-release capsules, hard

Boxes containing 20, 28, 30, 40 modified-release capsules, hard packed in blisters made of PVC/PVdC aluminium foil.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

MC Pharma (Pty) Ltd

Plot 87, 62 Constantia Avenue

Mnandi

Centurion

0157

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### **This leaflet was last revised in**

29 November 2021

### **Registration number(s):**

Medikinet MR 5 mg: 51/1.2/1088

Medikinet MR 10 mg: 51/1.2/1089

Medikinet MR 20 mg: 51/1.2/1090

Medikinet MR 30 mg: 51/1.2/1091

Medikinet MR 40 mg: 51/1.2/1092

Medikinet MR 50 mg: 51/1.2/1093

Medikinet MR 60 mg: 51/1.2/1094

## PASIËNTINLIGTINGSPAMFLET

### SKEDULERINGSSTATUS

S6

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**Bevat suiker:** 127.14 mg – 145.42 mg sukrose vir **Medikinet MR 10 mg** gemodifiseerde vrystellings kapsules

**Bevat suiker:** 114.65 mg – 131.13 mg sukrose vir **Medikinet MR 20 mg** gemodifiseerde vrystellings kapsules

**Bevat suiker:** 69.60 mg – 79.61 mg sukrose vir **Medikinet MR 30 mg** gemodifiseerde vrystellings kapsules

**Bevat suiker:** 92.80 mg – 106.14 mg sukrose vir **Medikinet MR 40 mg** gemodifiseerde vrystellings kapsules

**Bevat suiker:** 116.00 mg - 132.68 mg sukrose vir **Medikinet MR 50 mg** gemodifiseerde vrystellings kapsules

**Bevat suiker:** 139.20 mg - 159.22 mg sukrose vir **Medikinet MR 60 mg** gemodifiseerde vrystellings kapsules

▼ Hierdie medisyne is onderhewig aan addisionele monitering. Dit sal nuwe veiligheidsinligting vinnig identifiseer. U kan help deur newe-effekte wat u mag kry, aan te meld. Sien die einde van afdeling 4 vir inligting oor hoe om newe-effekte aan te meld.

**Lees hierdie hele pamflet sorgvuldig deur voordat u of u kind begin om MEDIKINET MR te neem, omdat dit belangrike inligting vir u bevat.**

- Hou hierdie pamflet. U moet dit dalk weer lees.
- Indien u enige verdere vrae het, vra u dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- MEDIKINET MR is vir u of u kind voorgeskryf. Moenie u medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al het hulle dieselfde simptome as u.
- Indien u enige newe-effekte ervaar, praat met u dokter of apteker. Dit sluit in enige moontlike newe-effekte nie in hierdie pamflet gelys nie. Sien afdeling 4.

Wat is in hierdie pamflet:

1. Wat MEDIKINET MR is en waarvoor dit gebruik word
2. Wat u moet weet voordat u of u kind MEDIKINET MR neem
3. Hoe om MEDIKINET MR te neem
4. Moontlike newe-effekte

5. Hoe om MEDIKINET MR te bêre
6. Inhoud van die verpakking en ander inligting

## **WAT MEDIKINET MR IS EN WAARVOOR DIT GEBRUIK WORD**

### **Wat Medikinet MR is**

**Medikinet MR 5 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 5 mg metielfenidaat hidrochloried, gelykstaande aan 4.35 mg metielfenidaat.

**Medikinet MR 10 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 10 mg metielfenidaat hidrochloried, gelykstaande aan 8.65 mg metielfenidaat.

**Medikinet MR 20 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 20 mg metielfenidaat hidrochloried, gelykstaande aan 17.30 mg metielfenidaat.

**Medikinet MR 30 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 30 mg metielfenidaat hidrochloried, gelykstaande aan 25.95 mg metielfenidaat.

**Medikinet MR 40 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 40 mg metielfenidaat hidrochloried, gelykstaande aan 34.60 mg metielfenidaat.

**Medikinet MR 50 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 50 mg metielfenidaat hidrochloried, gelykstaande aan 43.25 mg metielfenidaat.

**Medikinet MR 60 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 60 mg metielfenidaat hidrochloried, gelykstaande aan 51.90 mg metielfenidaat.

Farmakoterapeutiese groep: psigoanaleptika (A.1.2): psigostimulante, middels gebruik vir ATHV en nootropika; sentraalwerkende simpatomimetika

### **Waarvoor dit gebruik word**

MEDIKINET MR word gebruik om ‘aandagtekort hiperaktiwiteitsversteuring’ (ATHV) te behandel.

- dit word gebruik by kinders van 6 jaar en ouer en by volwassenes wat ATHV as kind gehad het.
- dit word slegs gebruik nadat ander behandelings wat nie medisyne behels nie, probeer is en onvoldoende wat bv. berading en gedragsterapie.

MEDIKINET MR is nie vir gebruik vir behandeling van ATHV by kinders onder 6 jaar oud nie.

### **Hoe dit werk**

MEDIKINET MR verbeter die werking van sekere dele van die brein wat onderaktief is. Die medisyne help om aandagspan en konsentrasie te verbeter en impulsiewe gedrag te verminder.

Die medisyne word gegee as deel van ‘n behandelingsprogram, wat gewoonlik sielkundige, opvoedkundige en sosiale terapie insluit.

MEDIKINET MR-behandeling moet slegs begin word deur, en gebruik word onder toesig van ‘n dokter, gespesialiseerd in die behandeling van ATHV, soos ‘n kundige pediater, ‘n

kinder- of adolessente psigiater of 'n psigiater. 'n Noukeurige ondersoek deur hierdie dokter is nodig. Indien u as volwassene nog nie voorheen behandel is nie, sal die dokter toetse uitvoer om te bevestig dat u sedert u kinderjare deur ATHV beïnvloed is. Alhoewel daar geen kuur vir ATHV is nie, kan dit beheer word deur behandelingsprogramme te gebruik.

## **Oor ATHV**

Kinders en jong mense met ATHV vind dit:

- moeilik om stil te sit en
- moeilik om te konsentreer.

Dit is nie hulle skuld dat hulle nie hierdie dinge kan doen nie.

Pasiënte kan in verskillende grade ATHV hê met simptome, insluitend:

- gebrek aan konsentrasie
- rusteloosheid
- hiperaktiwiteit
- impulsiwiteit
- emosionele onstabieleit
- ongeorganiseerde denke

Dit word getoon deur byvoorbeeld:

- moeilik om te konsentreer
- vergeetagtigheid
- praat te veel
- probleme met beplanning en uitvoering van take tot voltooiing
- blinddoek aksies
- ongeduld

ATHV beïnvloed nie die intelligensie van 'n kind of jongmens nie.

## **2. WAT U MOET WEET VOOR U OF U KIND MEDIKINET MR NEEM**

### **Moenie MEDIKINET MR neem**

#### **indien u of u kind**

- allergies is vir metielfenidaat of enige van die ander bestanddele van hierdie medisyne (gelys in afdeling 6)
- 'n skieldklierprobleem het
- verhoogde druk in die oog het (gloukom)
- 'n gewas van die byniere het (feochromositoon)
- 'n eetprobleem het as u nie honger voel of wil eet nie - soos 'anorexia nervosa'
- hoë bloeddruk of vernouing van die bloedvate het, wat pyn in die arms en bene kan veroorsaak
- ooit hartprobleme gehad het – soos 'n hartaanval, ongelyke hartklop, pyn en ongemak in die bors, hartversaking, hartsiekte of met 'n hartprobleem gebore is
- 'n probleem met bloedvate in die brein gehad het – soos 'n beroerte, swelling en verswakking van 'n deel van 'n bloedvat (aneurisme), nou of geblokkeerde bloedvate, of inflammasie van die bloedvate (vaskulitis)
- tans of in die laaste 14 dae 'n antidepressant geneem het (bekend as 'n monoamienoksidase inhibeerder) – sien 'Sien ander medisyne en MEDIKINET MR'

- geestesgesondheidsprobleme het, soos:
  - ‘n ‘psigopatiese’ of ‘grenslyn persoonlikheids’ probleem het
  - abnormale gedagtes of visioene of ‘n siekte wat ‘skisofrenie’ genoem word
  - tekens van ‘n ernstige gemoedsprobleem soos:
    - voel om jouself dood te maak
    - ernstige depressie, waar u baie hartseer, waardeloos en hopeloos voel
    - manie, waar u ongewoon opgewonde, ooraktief, en onbelemmerd voel.
- ‘n geskiedenis van merkbare gebrek aan maagsuur het (anasiditeit van die maag) met ‘n pH-waarde bo 5.5
- medisyne neem om die afskeiding van maagsuur te verminder of die oormatige suurheid van die maag te behandel (H2 reseptorblokker, protonpompremmer of teensuurbehandeling)
- indien die pasiënt swanger is of hulle baba borsvoed

Moenie MEDIKINET MR neem indien enige van bogenoemde op u of u kind van toepassing is nie. Indien u onseker is, raadpleeg u dokter of apteker voordat u of u kind metielfenidaat neem. Dit is omdat MEDIKINET MR hierdie probleme kan vererger. Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per doserings eenheid, dit wil sê in wese natriumvry.

### **Waarskuwings en voorsorgmaatreëls**

Raadpleeg u dokter voordat MEDIKINET MR geneem word, indien u of u kind

- lewer- of nierprobleme het
- probleme het met sluk of om tablette heel te sluk
- ‘n vernouing of verstopping van die ingewande of voedselpyp
- stuipe (aanvalle, konvulsies, epilepsie) of enige abnormale breinskanderings (EEGs) gehad het
- ooit alkohol, voorskrifmedisyne of straatdwelms misbruik het of daarvan afhanklik was
- vroulik is en periodes begin kry het (sien die ‘Swangerskap en borsvoeding’ afdeling hieronder)
- moeilik-om-te-beheer, herhaalde rukkings van enige dele van die liggaam of herhaalde klanke en woorde het
- hoë bloeddruk het
- ‘n hartprobleem het wat nie in die ‘Moenie neem’ afdeling hierbo is nie
- ‘n geestesgesondheidsprobleem het wat nie in die ‘Moenie neem’ afdeling hierbo is nie. Ander geestesgesondheidsprobleem sluit in:
  - gemoedswisselings (van manies tot depressief wees - wat ‘bipolêre versteuring’ genoem word)
  - begin om aggressief or vyandig te word, of aggressie vererger
  - sien, hoor of voel dinge wat nie daar is nie (hallusinasies)
  - glo dinge wat nie waar is nie (waanidee)
  - ongewoon agterdogtig voel (paranoia)
  - geagiteerd, angstig of gespanne voel
  - depressief of skuldig voel.

Vertel u dokter of apteker indien enige van bogenoemde op u of u kind van toepassing is voordat u met die behandeling begin. MEDIKINET MR kan hierdie probleme vererger. U dokter sal monitor hoe hierdie medisyne u of u kind beïnvloed.

### **Kontroles wat u dokter sal doen voordat u MEDIKINET MR begin neem**

Hierdie kontroles is om te besluit of MEDIKINET MR die korrekte medisyne vir u of u kind. U dokter sal met u praat oor:

- enige ander medisyne wat u of u kind neem
- of daar 'n familiegeskiedenis van skielik onverklaarbare dood is
- enige ander mediese probleme (soos hartprobleme) wat u of u familie mag hê
- hoe u of u kind voel, soos om hoog of laag te voel, om vreemde gedagtes te hê of indien u of u kind enige van hierdie gevoelens in die verlede gehad het
- of daar 'n familiegeskiedenis van 'tiefs' is (moeilik-om-te-beheer, herhaalde rukking van enige dele van die liggaam of herhaalde klanke en woorde)
- enige geestesgesondheid- of gedragsprobleme wat u of u kind of ander familielede ooit gehad het.

U dokter sal bespreek of u of u kind 'n risiko loop om gemoedswisselings te hê (van manies tot depressief wees – wat 'bipolêre versteuring' genoem word). Hulle sal u of u kind se geestesgesondheidsgeskiedenis nagaan, en kyk of enige van u familie 'n geskiedenis van selfmoord, bipolêre versteuring of depressie het.

Dit is belangrik dat u so veel as moontlik inligting verskaf. Dit sal u dokter help om te besluit of MEDIKINET MR die korrekte medisyne vir u of u kind is. U dokter kan besluit dat ander mediese toetse benodig word voordat u of u kind hierdie medisyne begin neem.

Tydens die behandeling kan seuns of adolessente onverwags langdurige ereksies hê. Dit kan pynlik wees en enige tyd voorkom. Dit is belangrik om u dokter onmiddellik te kontak indien u ereksie langer as 2 uur duur, veral as dit pynlik is.

### **Dwelmtoetsing**

MEDIKINET MR kan 'n positiewe uitslag gee wanneer vir dwelmgebruik getoets word. Atlete moet bewus wees dat hierdie medisyne 'n positiewe reaksie op 'antidoping'-toetse kan veroorsaak.

### **Ander medisyne en MEDIKINET MR**

Vertel asseblief u dokter of apteker indien u of u kind enige ander medisyne neem of onlangs geneem het of moontlik neem.

### **Moenie MEDIKINET MR neem indien u of u kind:**

- medisyne neem wat 'monoamienoksidase inhibeerder' (MAOI) genoem word, gebruik vir depressie, of indien 'n MAOI in die laaste 14 dae geneem is. Die neem van 'n MAOI met MEDIKINET MR kan 'n skielike toename in bloeddruk veroorsaak.

Indien u of u kind ander medisyne neem, kan MEDIKINET MR 'n invloed hê oor hoe goed dit werk of kan dit nuwe-effekte veroorsaak. Vertel u dokter indien u of u kind medisyne neem om die volgende te behandel:

- depressie
- geestesgesondheidsprobleme
- epilepsie
- bloeddrukprobleme
- hoes en verkoue; sommige remedies kan middels bevat wat bloeddruk kan beïnvloed. Dit is belangrik om met u apteker te konsulteer wanneer u enige van hierdie medisyne koop.
- medisyne wat u bloed verdun om bloedklonte te voorkom

MEDIKINET MR moet nie saam met H<sub>2</sub>-reseptorblokkers, protonpomprenners of

teensuurmiddels, wat gebruik word of maagsuur afskeiding te verminder of om oormatige suurheid in die maag teen te werk, gebruik nie, aangesien dit kan lei tot vinniger vrystelling van die totale hoeveelheid aktiewe bestanddeel.

Indien u twyfel of enige van die medisyne wat u of u kind neem in bogenoemde lys ingesluit is, vra u dokter of apteker vir advies voordat u MEDIKINET MR neem.

### **Operasie te ondergaan**

Vertel u dokter indien u of u kind 'n operasie gaan hê. MEDIKINET MR moet nie op die dag van die operasie geneem word indien sekere tipe narkose gebruik word nie. Dit is omdat daar 'n kans is van skielike styging van bloeddruk tydens die operasie.

### **Die neem van MEDIKINET MR met alkohol**

Moenie alkohol drink terwyl u hierdie medisyne neem nie. Alkohol kan die nuwe-effekte van hierdie medisyne vererger. Onthou dat sommige voedsel en medisyne alkohol bevat.

### **Swangerskap en borsvoeding**

MEDIKINET MR moet nie tydens swangerskap of borsvoeding geneem word nie. Vertel u dokter of apteker

voordat MEDIKINET MR geneem word indien u of u dogter:

- seks het. U dokter sal voorbehoeding bespreek.
- swanger is of dink dat sy dalk swanger is
- borsvoed of beplan om te borsvoed. Dit is moontlik dat metielfenidaat in menslike borsmelk oordra.

### **Bestuur en gebruik van masjinerie**

U of u kind kan duiselig voel, probleme ondervind met fokus of dowwe visie hê terwyl MEDIKINET MR geneem word. Indien dit gebeur, moet u nie bestuur, masjiene gebruik, fiets- of perdry of bome klim nie.

### **MEDIKINET MR bevat sukrose**

Indien u dokter u meegedeel het dat u of u kind 'n intoleransie vir sommige suikers het, raadpleeg u dokter voordat u hierdie medisinale produk begin neem.

## **3. HOE OM MEDIKINET MR TE NEEM**

U of u kind moet MEDIKINET MR altyd neem presies soos u dokter u gesê het. U moet u dokter of apteker raadpleeg indien u onseker is.

### **Dosis**

#### Gebruik by kinders

Die maksimum daaglikse dosis is 60 mg.

- u dokter sal gewoonlik begin met 'n lae dosis behandeling en dit geleidelik verhoog soos nodig.
- u dokter sal u vertel watter sterkte kapsule u elke dag moet neem.
- moenie die dosis van 'n kapsule verdeel nie; neem die hele inhoud.

- MEDIKINET MR moet nie te laat in die oggend geneem word nie, aangesien dit slaapstoornisse kan veroorsaak.

#### Gebruik by volwassenes

##### Vir volwassenes wat MEDIKINET MR voorheen geneem het

- indien u reeds as kind of adolessent MEDIKINET MR geneem het, kan dieselfde daaglikse dosis (mg/dag) gebruik word; u dokter sal gereeld kyk of enige aanpassing benodig word.
- volwasse pasiënte benodig moontlik hoër daaglikse dosis, maar die dokter wil u die laagste effektiewe dosis gee.
- die maksimum daaglikse dosis is onder meer gebaseer op u liggaamsgewig (sien hieronder).

##### Vir volwassenes wat nog nie MEDIKINET MR voorheen gebruik het nie

Die aanbevole aanvangsdosis is 10 mg daagliks.

- u dokter sal u dosis in inkremente van 10 mg per dag verhoog, afhangende van hoe goed u die medisyne verdra en hoe effektief dit is.
- die doel moet die laagste dosis wees wat vir u effektief is.
- die maksimum daaglikse dosis is onder meer gebaseer op u liggaamsgewig (sien hieronder).
- u dokter sal die maksimum daaglikse dosis vir u bepaal.
- die daaglikse dosis is 1 mg per kg liggaamsgewig, tot 'n maksimum van 80 mg van metelfenidaat daagliks.

#### **Dinge wat u dokter sal doen indien u of u kind met behandeling begin**

##### **U dokter sal toetse doen**

- voordat u of u kind begin – om seker te maak dat MEDIKINET MR veilig is en tot voordeel sal wees.
- nadat u of u kind begin het – sal dit minstens elke 6 maande gedoen word, maar moontlik ook meer indien die dosis verander word.
- hierdie toetse sal insluit:
  - kyk na eetlus
  - meet lengte en gewig van kinders
  - meet gewig van volwassenes
  - meet bloeddruk en hartklop
  - nagaan van probleme met gemoed, gemoedstoestand of ander ongewone gevoelens. Of indien hierdie vererger tydens die neem van MEDIKINET MR.

#### **Metode van Toediening**

Die medisyne is bedoel vir orale gebruik.

Kinders neem MEDIKINET MR in die oggend **met of sonder** ontbyt.

Volwassenes neem MEDIKINET MR met of na ontbyt **en** middagete.

MEDIKINET MR is 'n vorm van metielfenidaat met “gekontroleerde vrystellings” werking wat die medisyne geleidelik oor 'n lang tydperk vrystel. Dit is belangrik om die kapsule met of na etes te neem, sodat die werking daarvan vertraag word.

Die kapsule kan heel ingesluk word met 'n glas water. U kan ook die kapsules oppmaak, die inhoud op 'n klein hoeveelheid (eetlepel) van appelmoes of jogurt strooi en dit onmiddellik neem. Moenie bêre vir toekomstige gebruik nie.

Die kapsules en inhoud van die kapsule moet nie fyngedruk of gekou word nie.

### **Indien u of u kind nie beter voel na 1 maand van behandeling nie**

Indien u of u kind nie beter voel nie, vertel u dokter. Hulle kan dalk besluit dat 'n ander behandeling nodig is.

### **Langtermyn behandeling**

MEDIKINET MR hoef nie vir altyd geneem te word nie. Indien u of u kind MEDIKINET MR vir meer as 'n jaar neem, moet u dokter ten minste een keer per jaar u behandeling vir 'n kort tydperk staak. In die geval van kinders kan dit tydens 'n skoolvakansie gebeur. Dit sal wys of die medisyne nog nodig is.

### **Indien MEDIKINET MR nie behoorlik gebruik word nie**

Indien MEDIKINET MR nie behoorlik gebruik word nie, kan dit abnormale gedrag veroorsaak. Dit kan ook beteken dat u of u kind begin om van die medisyne afhanklik te raak. Vertel u dokter indien u of u kind ooit alkohol, voorskrifmedisyne of straatdwelms misbruik het of daarvan afhanklik was.

### **Indien u of u kind meer MEDIKINET MR neem as wat u moet**

Indien u of u kind te veel van die medisyne neem, moet u onmiddellik 'n dokter raadpleeg of 'n ambulans kontak. vertel hulle hoeveel daar geneem is.

Tekens van oordosis kan insluit: siek wees, geagiteerd voel, skudding, verhoogde onbeheerde bewegings, spiertrekkings, stuipe (kan gevolg word deur koma), baie gelukkig voel, verward wees, sien, voel en hoor dinge wat nie regtig is nie (hallusinasies), sweet, gloede, hoofpyn, hoë koors, veranderinge in hartklop (stadig, vinnig of ongelyk), hoë bloeddruk, verwydde pupille en droë neus en mond.

### **Indien u of u kind vergeet om MEDIKINET MR te neem**

Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie. Indien u of u kind 'n dosis vergeet, wag totdat dit tyd is vir die volgende dosis.

### **Indien u of u kind ophou om MEDIKINET MR te neem**

Indien u of u kind skielik ophou om die medisyne te neem, kan ATHV simptome terugkeer of kan ongewenste simptome soos depressie voorkom. U dokter sal moontlik die hoeveelheid medisyne wat u daaglik neem geleidelik verminder, voordat u heeltemal stop. Raadpleeg u dokter voordat u MEDIKINET MR stop.

Raadpleeg u dokter of apteker, indien u nog vrae het oor die gebruik van hierdie medisyne.

## **4. MOONTLIKE NEWE-EFFEKTE**

Hierdie medisyne kan newe-effekte hê. U dokter sal met u praat oor hierdie newe-effekte.

**Sommige newe-effekte kan ernstig wees. Indien u enige van die onderstaande newe-effekte ervaar, raadpleeg u dokter onmiddellik:**

### **Gereelde newe-effekte**

- ongelyke hartklop (palpitاسies)
- gemoedsveranderinge

### **Minder gereelde newe-effekte**

- gemoedswisselings
- veranderinge in persoonlikheid
- sien, voel of hoor dinge wat nie werklik is nie – hierdie is tekens van psigose
- onbeheerde spraak en liggaamsbewegings (Tourette's) of verergering daarvan
- borspyn
- tekens van allergie soos uitslag, jeuk of velbulte op die vel, swelling van die gesig, lippe, tong of ander dele van die liggaam, kortasem, hyging of moeilik om asem te haal
- dink daaraan of voel dat u uself wil doodmaak
- ongewoon opgewonde, ooraktief en onbelemmerd voel (manie)
- hartaanval
- stuipe (aanvalle, konvulsies, epilepsie)
- velafskilfering of pers-rooi kolle
- spierspasmas wat u nie kan beheer nie, wat u oë, kop, nek, liggaam en senuweestelsel beïnvloed – as gevolg van 'n tydelike gebrek aan bloetoevoer na die brein
- verlamming of probleme met beweging en visie, moeilike spraak (hierdie kan tekens wees van probleme met bloedvate in u brein), tydelike gebrek aan voldoende bloed en suurstof (isgemie) na die brein
- afname in aantal bloedselle (rooiselle, witselle en plaatjies) wat u meer geneig kan maak om infeksies te kry, en u makliker laat bloei en kneus
- 'n skielike toename in liggaamstemperatuur, baie hoë bloeddruk en ernstige konvulsies ('Neuroleptiese Maligne Sindroom').

### **Onbekend: frekwensie kan nie uit beskikbare data beraam word nie**

- ongewenste effekte wat aanhou terugkeer
- onverklaarbare floute, kortasem (hierdie kan tekens van hartprobleme wees)

Indien u enige van die bogenoemde newe-effekte ervaar, raadpleeg u dokter onmiddellik.

### **Onder newe-effekte sluit die volgende in, indien dit ernstig word, raadpleeg asseblief u dokter of apteker:**

#### **Gereelde newe-effekte**

- hoofpyn
- senuweeagtig voel
- nie kan slaap nie
- verminderde eetlus
- geagiteerd voel,
- depressief voel of gebrek aan gevoel of emosie of toon min belangstelling
- droë mond
- siek voel
- gewrigspyn
- hoë temperatuur (koors)
- ongewone haarverlies of verdunning
- ongewoon slaperig of lomerig voel
- paniek aanval
- tandpyn
- jeuk, uitslag of verhoogde rooi jeukerige uitslag (velbulte)

- hoes, seer keel of neus en keelirritasie
- hoë bloeddruk of ander veranderinge in bloeddruk,
- vinnige hartklop (tagikardie) of onreëlmatige hartklop (aritmie)
- duiselig voel,
- bewegings wat u nie kan beheer nie,
- buitengewoon aktief wees
- aggressief emosioneel onstabiel, angstig, gestres, geïrriteerd voel
- abnormaal optree
- maagpyn, diaree, maagongemak, slegte spysvertering, dors, braking
- gebrek aan eetlus/nie bereid om te eet
- gewigsverlies
- oormatige tande kners (bruxisme)
- oormatige kneus

### **Minder gereelde newe-effekte**

- skud of bewe
- dowwe visie
- spierpyn
- hardlywigheid
- inflammasie van die slymvliese van maag en dunderm
- ekstra geluid tydens hartklop (gebaseer op ondersoekbevindinge)
- bloed in die urine
- dubbel visie
- spiertrekkings
- spier styfheid
- kortasem of borspyn
- toename in lewertoetsresultate (sien in 'n bloedtoets)
- woede
- tranerig voel
- rusteloos voel,
- oormatige bewustheid van die omgewing
- baie kalm of slaperig voel
- probleme met slaap in die algemeen
- moegheid
- spanning
- veranderinge in seksdrang
- gedisorïenteerd voel
- verwydde pupille, sukkel om te sien
- swelling van die borste in mans
- rooiheid van die vel, rooi opgehewe veluitslag
- pyn as gevolg van onvoldoende bloedvloei na die hart
- probleme/veranderinge in die menstruasie
- hartaanval
- skielike dood
- spierkrampe
- klein rooi merke op die vel
- inflammasie of geblokkeerde are in die brein
- abnormale lewerfunksie insluitend lewersaking en koma
- veranderinge in toetsresultate – insluitend lewer- en bloedtoetse
- selfmoordpoging
- abnormale denke
- doen dinge oor en weer oor

- obsessief te wees oor een ding
- gebrek aan energie
- voel hartseer oor 'n kort tydjie
- fingers en tone voel gevoelloos en koud, tintelend en veranderde kleur (van wit tot blou, dan rooi) wanneer koud ('Raynaud se verskynsel')

**Onbekend: frekwensie kan nie uit beskikbare data beraam word nie**

- migraine
- baie hoë koors
- stadige, vinnige of ekstra hartkloppe
- 'n groot aanval ('grand mal konvulsies')
- glo dinge wat nie waar is nie
- verwardheid
- hartseer/donker gedagtes
- 'n liggaamlike behoefde aan die medisyne of voel die afwesigheid daarvan
- probleme met bloedvate van die brein (beroerte, serebrale arteritis of serebrale okklusie)
- droë vel
- erekteie disfunksie
- langdurige ereksies, somtyds pynlik, of 'n groter aantal ereksies
- oormatige onbeheerde praat
- spanning
- kners u tande tydens slaap
- ATHV simptome kan terugkeer of ongewensde effekte soos depressie kan voorkom nadat die medisyne gestop is
- tintelinde sensasie
- probleme met taal en spraak
- braking waar niks uitkom nie
- aandagversteuring
- griepagtige siekte
- verlies van energie / swak voel
- dors voel
- toename in bloedseldklier stimulerende hormoonvlakke
- pyn in die mond en keel
- neusbloeding
- hartongemak
- droë oog
- hoër drukking binne die oog as normaal
- stres met maat / familie
- borspyn
- warm gloed / gloede
- lui in die ore (tinnitus)
- mishandeling
- pansitopenie (abnormale afname in die vlakke van all soorte bloedselle)
- onvermoë om die uitskeiding van urine te beheer (inkontinensie)
- spasma van die kaakspiere wat dit moeilik maak om die mond oop te maak (trismus)
- hakkel

**Uitwerking op groei**

Wanneer vir meer as 'n jaar gebruik word, kan MEDIKINET MR groei in sekere kinders verminder.

- Daar kan 'n gebrek aan gewigstoename of lengte wees.
- U dokter sal noukeurig na u en u kind se lengte en gewig kyk, asook hoe goed u of u kind eet.
- Indien u of u kind nie groei soos verwag nie, kan die behandeling met MEDIKINET MR gestop word.

### **Aanmelding van nuwe-effekte**

Aanmelding van vermoedelike nadelige reaksies na die goedkeuring van medisyne deur die owerheid is belangrik. Dit laat voortdurende monitering van die voordeel/risiko-balans van die medisyne toe. Gesondheidsorgverskaffers word versoek om enige vermoedelike nadelige reaksies aan SAHPRA via die “**6.04 Adverse Drug Reactions Reporting Form**”, wat aanlyn gevind kan word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>.

Daarbenewens kan vermoedelike nuwe-effekte aangemeld word aan die Houer van Registrasiesertifikaat via [pv@mcpharma.co.za](mailto:pv@mcpharma.co.za).

## **5. HOE OM MEDIKINET MR TE BÊRE**

Hou hierdie medisyne buite sig en bereik van kinders.

Moenie hierdie medisyne gebruik na die vervaldatum wat op die stulpstrook en boks na “EXP” aangedui is nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Bêre teen of benede 30 °C.

Bêre in die oorspronklike verpakking om teen vog te beskerm.

Moenie enige medisyne via afvalwater of huishoudelike afval weggooi nie. Vra u apteker oor hoe om medisyne wat u nie meer gebruik nie, weg te gooi. Hierdie maatreëls sal help om die omgewing te beskerm.

## **6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING**

**Wat MEDIKINET MR bevat:**

**Die aktiewe bestanddeel is:** metielfenidaat hidrochloried

**Medikinet MR 5 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 5 mg metielfenidaat hidrochloried, gelykstaande aan 4.35 mg metielfenidaat.

**Medikinet MR 10 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 10 mg metielfenidaat hidrochloried, gelykstaande aan 8.65 mg metielfenidaat.

**Medikinet MR 20 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 20 mg metielfenidaat hidrochloried, gelykstaande aan 17.30 mg metielfenidaat.

**Medikinet MR 30 mg** gemodifiseerde vrystellings kapsules, hard

Elke gemodifiseerde vrystellings kapsule, hard bevat 30 mg metielfenidaat hidrochloried, gelykstaande aan 25.95 mg metielfenidaat.

**Medikinet MR 40 mg** gemodifiseerde vrystellings kapsules, hard  
Elke gemodifiseerde vrystellings kapsule, hard bevat 40 mg metielfenidaat hidrochloried, gelykstaande aan 34.60 mg metielfenidaat.

**Medikinet MR 50 mg** gemodifiseerde vrystellings kapsules, hard  
Elke gemodifiseerde vrystellings kapsule, hard bevat 50 mg metielfenidaat hidrochloried, gelykstaande aan 43.25 mg metielfenidaat.

**Medikinet MR 60 mg** gemodifiseerde vrystellings kapsules, hard  
Elke gemodifiseerde vrystellings kapsule, hard bevat 60 mg metielfenidaat hidrochloried, gelykstaande aan 51.90 mg metielfenidaat.

**Die ander bestanddele is:**

**Kapsule-inhoud:**

Suikersfere (bevat sukrose en mieliestysel), Metakrielsuur-etielakrylaat-kopolimeer (1:1), Talk, Trietielsitraat, Poli(vinielalkohol), Makrogol 3350, Polisorbaat 80, Natriumhidroksied, Natriumlaurielsulfaat, Simetikoon, Silika kolloidale watervry, Metielsellulose, Sorbiensuur, Indigo karmyn, aluminiumlak (E 132)

**Kapsule-dop:**

Gelatien, Titaandioksied (E 171), Natriumlaurielsulfaat, Gesuiwerde water

addisioneel in die kapsule-dop van MEDIKINET MR 10 mg /- 20 mg:  
Eritrosien (E 127), Patent blou V (E 131)

addisioneel in die kapsule-dop van MEDIKINET MR 30 mg /- 40 mg /- 50 mg /- 60 mg:  
Eritrosien(E 127), Ysteroksied swart (E 172), Indigo karmyn (E 132)

**Hoe MEDIKINET MR lyk en inhoud van die verpakking:**

**MEDIKINET MR 5 mg** gemodifiseerde vrystellings kapsules, hard  
Wit ondeursigtige kapsule-romp/wit ondeursigtige kapsule-dop (15.9 mm) wat wit en blou korrels bevat.

**MEDIKINET MR 10 mg** gemodifiseerde vrystellings kapsules, hard  
Wit ondeursigtige kapsule-romp/ligrooi ondeursigtige kapsule-dop (15.9 mm) wat wit en blou korrels bevat.

**MEDIKINET MR 20 mg** gemodifiseerde vrystellings kapsules, hard  
Ligrooi ondeursigtige kapsule-romp/ligrooi ondeursigtige kapsule-dop (15.9 mm) wat wit en blou korrels bevat.

**MEDIKINET MR 30 mg** gemodifiseerde vrystellings kapsules, hard  
Liggrys ondeursigtige kapsule-romp/donker violet ondeursigtige kapsule-dop (15.9 mm) wat wit en blou korrels bevat.

**MEDIKINET MR 40 mg** gemodifiseerde vrystellings kapsules, hard  
Grys ondeursigtige kapsule-romp/donker violet ondeursigtige kapsule-dop (18.0 mm) wat wit en blou korrels bevat.

**MEDIKINET MR 50 mg** gemodifiseerde vrystellings kapsules, hard  
Violet ondeursigtige kapsule-romp/donker violet ondeursigtige kapsule-dop (18.0 mm) wat wit en blou korrels bevat.

**MEDIKINET MR 60 mg** gemodifiseerde vrystellings kapsules, hard  
Donker violet ondeursigtige kapsule-romp/donker violet ondeursigtige kapsule-dop (19.4 mm) wat wit en blou korrels bevat.

Verpakkingsgroottes:

**MEDIKINET MR 5 mg** gemodifiseerde vrystellings kapsules, hard  
Bokse wat 20, 30 of 50 gemodifiseerde vrystellings kapsules, hard bevat, verpak in stulpstrokke gemaak van PVC/PVdC aluminiumfoelie.

**MEDIKINET MR 10 mg /- 20 mg /- 30 mg /- 40 mg** gemodifiseerde vrystellings kapsules, hard  
Bokse wat 20, 28, 30 of 50 gemodifiseerde vrystellings kapsules, hard bevat, verpak in stulpstrokke gemaak van PVC/PVdC aluminiumfoelie.

**MEDIKINET MR 50 mg /- 60 mg** gemodifiseerde vrystellings kapsules, hard  
Bokse wat 20, 28, 30, 40 gemodifiseerde vrystellings kapsules, hard bevat, verpak in stulpstrokke gemaak van PVC/PVdC aluminiumfoelie.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

#### **Houer van Registrasiesertifikaat**

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#### **Hierdie pamflet is laas hersien in**

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#### **Registrasienommer(s):**

Medikinet MR 5 mg	51/1.2/1088
Medikinet MR 10 mg	51/1.2/1089
Medikinet MR 20 mg	51/1.2/1090
Medikinet MR 30 mg	51/1.2/1091
Medikinet MR 40 mg	51/1.2/1092
Medikinet MR 50 mg	51/1.2/1093
Medikinet MR 60 mg	51/1.2/1094