

PATIENT INFORMATION LEAFLET

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,

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▼ 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

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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

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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.

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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)

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- 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:
 - feeling like killing yourself
 - severe depression, where you feel very sad, worthless and hopeless
 - mania, where you feel unusually excitable, over-active, and un-inhibited.
- 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)
- 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.

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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.

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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.

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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.

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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 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

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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

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- 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.

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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

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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

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- 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

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- 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

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- 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

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- 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

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- 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

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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 Adcock.AEReports@adcock.com.

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.

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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.

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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.

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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

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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

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860/ADCOCK 232625

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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

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Medikinet MR 40 mg: 51/1.2/1092

Medikinet MR 50 mg: 51/1.2/1093

Medikinet MR 60 mg: 51/1.2/1094