

Method of Administration

The medicinal product is intended for oral use.

Children take Medikinet XL in the morning **with or after** breakfast.

Adults take Medikinet XL with or after breakfast **and** lunch.

Medikinet XL 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 (teaspoon) of applesauce or yoghurt and take it immediately. Do not store for future use.

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

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

If you or your child does not feel better after 1 month of treatment, tell your doctor. Your doctor may decide that you or your child needs a different treatment.

Long-term treatment

Medikinet XL does not need to be taken for ever. If you or your child takes Medikinet XL 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 XL properly

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

This medicine is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

If you or your child takes more Medikinet XL than you should

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

Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth, muscle spasms, fever and reddish-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you or your child forgets to take Medikinet XL

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 XL

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 XL.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, but not everybody gets them. Your doctor will talk to you about these side effects.

Some side effects could be serious. If you have any of the side effects below, see a doctor straight away:

Common: may affect up to 1 in 10 people

- uneven heartbeat (palpitations)
- changes in personality
- excessive teeth grinding (bruxism)

Uncommon: may affect up to 1 in 100 people

- mood swings, mood changes
- thinking about or feeling like killing yourself
- 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

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

- feeling unusually excited, over-active and un-inhibited (mania)

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

- heart attack
- fits (seizures, epilepsy with convulsions)
- 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'). It is not certain whether this side effect is caused by methylphenidate or other drugs that may be taken in combination with methylphenidate.

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:

Very common: may affect more than 1 in 10 people

- decreased appetite
- headache
- feeling nervous
- not being able to sleep
- dry mouth
- being sick

Common: may affect up to 1 in 10 people

- feeling depressed or lack of feeling or emotion or showing much interest
- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite
- panic attack
- reduced sex drive
- toothache
- itching, rash or raised red itchy rashes (hives)
- cough, sore throat or nose and throat irritation, shortness of breath or chest pain
- changes in blood pressure (usually high blood pressure)
- fast heart beat (tachycardia), cold hands and feet
- shaking and trembling, feeling dizzy
- movements which you cannot control, feeling of inner restlessness
- being unusually active
- feeling aggressive, agitated, restless, emotional unstable, anxious, depressed, stressed, irritable and abnormal behaviour, problems sleeping, fatigue
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst, vomiting. These usually occur at the beginning of treatment and may be reduced by taking the medicine with food.
- lack of appetite/not willing to eat
- weight loss
- excessive sweating

Uncommon: may affect up to 1 in 100 people

- muscle pain, muscle twitching, muscle tightness
- constipation
- chest discomfort
- 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 or blurred vision
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings, tension
- feeling very calm or sleepy
- problems with the sleep in general
- fatigue

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

- 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

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

- heart attack
- sudden death
- muscle cramps
- small red marks on the skin
- inflammation or blocked arteries in the brain
- abnormal liver function including liver failure and coma
- changes in test results – including liver and blood tests
- suicidal attempt, (including completed suicide), abnormal thinking, lack of feeling or emotion, 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)
- erectile dysfunction
- prolonged erections, sometimes painful, or an increased number of erections
- excessive uncontrolled talking
- 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, methylphenidate may cause reduced growth in some children. This affects less than 1 in 10 children.

- there may be lack of weight gain or height
- 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 methylphenidate may be stopped for a short time.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Medikinet XL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the box after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

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

If your capsules become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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 XL contains:

The active substance is: methylphenidate hydrochloride

Medikinet XL 10 mg modified-release capsules, hard

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

Medikinet XL 20 mg modified-release capsules, hard

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

Medikinet XL 30 mg modified-release capsules, hard

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

Medikinet XL 40 mg modified-release capsules, hard

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

The other ingredients are:

Capsule content:

Sugar spheres (Maize starch and Sucrose), Methacrylic acid – ethyl acrylate copolymer (1:1), Talc, Triethyl citrate, Polyvinyl alcohol, Macrogol 3350, Polysorbate 80, Sodium hydroxide, Sodium laurilsulfate, Simeicone, Colloidal anhydrous silica, Methylcellulose, Sorbic acid, Indigo carmine aluminium lake E132.

Capsule shell:

Gelatin, Erythrosine (E127), Titanium dioxide (E171), Sodium laurilsulfate, Purified water

additional in the capsule shell of Medikinet XL 10 mg and 20 mg:

Patent blue V (E131).

additional in the capsule shell of Medikinet XL 30 mg and 40 mg:

Iron oxide black (E172)

Indigo carmine (E132)

What Medikinet XL looks like and contents of the pack

Medikinet XL 10 mg modified-release capsules, hard

White opaque capsule body/mauve opaque capsule cap containing white and blue pellets.

Medikinet XL 20 mg modified-release capsules, hard

Mauve opaque capsule body/mauve opaque capsule cap containing white and blue pellets.

Medikinet XL 30 mg modified-release capsules, hard

Light grey opaque capsule body/dark violet opaque capsule cap containing white and blue pellets.

Medikinet XL 40 mg modified-release capsules, hard

Dark grey opaque capsule body/dark violet opaque capsule cap containing white and blue pellets.

Pack sizes:

Boxes containing 27, 30, or 36 modified-release capsules, hard

Manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG,
Kuhloweg 37, 58638 Iserlohn, Germany.

Procured from within the EU.

Product Licence Holder, and repackaged by:
Cross Healthcare Ltd., Unit 2a, Bandeath Industrial Estate, Throsk,
Stirling, FK7 7NP, UK.

PL 20504/0003 Medikinet® XL 10 mg modified-release capsules, hard
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PL 20504/0005 Medikinet® XL 30 mg modified-release capsules, hard
PL 20504/0006 Medikinet® XL 40 mg modified-release capsules, hard



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How do I take my medicine (capsules)?

- Swallow your medicine with water with or **after a meal**.
- If you have problems to swallow the capsules, the capsules may be opened, the capsule contents sprinkled onto a small amount (teaspoon) of applesauce or yoghurt and taken immediately.

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

- Your doctor will tell you how many times a day you should take your medicine.
- Do not stop taking the medicine without talking to your doctor first.

Possible side effects

Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult you trust straight away. They can then talk to your doctor. The main things that could affect you are:

- Feeling worried or nervous
- Feeling dizzy, or getting head aches
- Being very depressed and unhappy or wanting to hurt yourself
- Having different moods than usual, not being able to get to sleep
- Skin rashes, bruising easily, getting out of breath
- The medicine can also make you feel **sleepy**. If you feel sleepy, it is important **not to do outdoor sports** like riding a horse or bike, swimming or climbing trees. You could hurt yourself and others.

- Your heart beating faster than usual
- When you are a boy, having pain at your penis or seeing different behaviour of your penis.

If you feel unwell in any way while you are taking your medicine please tell an adult you trust straight away.

Other things to remember

- make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.
- the medicine is special for you - **do not let anyone else have it**. It may help you, but it could hurt someone else.
- if you forget to take your medicine **don't** take two capsules the next time. Just take one capsule at the next normal time.
- if you do take too much medicine, tell your mum, dad or carer **right away**.
- it is important not to take too much medicine or you will get ill.
- don't stop taking your medicine until your doctor says it's OK.

Who should I ask if there is anything I don't understand?

Your mum, dad, carer, doctor, nurse or pharmacist will be able to help you.