**Package leaflet: Information for the user**

# Kiegia XL 10 mg modified-release hard capsules
# Kiegia XL 20 mg modified-release hard capsules
# Kiegia XL 30 mg modified-release hard capsules
# Kiegia XL 40 mg modified-release hard capsules
# Kiegia XL 60 mg modified-release hard capsules

Methylphenidate hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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 Kiegia XL are and what it is used for
2. What you need to know before you take Kiegia XL
3. How to take Kiegia XL
4. Possible side effects
5. How to store Kiegia XL
6. Contents of the pack and other information


## 1. What Kiegia XL are and what it is used for

The name of this medicine is Kiegia XL, it contains the active substance 'methylphenidate hydrochloride'. The name 'methylphenidate' is also use this leaflet.

**What it is used for**

Kiegia XL is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).
- It is used in children and adolescents between the ages of 6 and 18, and in adults.
- It is used only after treatments which do not involve medicine, such as counselling and behavioural therapy, and which have been insufficient.

Kiegia XL is not for use as a treatment for ADHD in children under 6 years of age. It is not known if it is safe or of benefit in these children under 6 years of age.

**How it works**

Kiegia XL 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.

Kiegia XL 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 are an adult and have not been treated before, the doctor will carry out tests to confirm that you have had ADHD since childhood. Using treatment programmes as well as medicine helps to manage ADHD.

**About ADHS**

Children and adolescents with ADHD find it hard:
- to sit still
- to concentrate

It is not their fault that they cannot do these things.

Many children and adolescents struggle to do these things. However ADHD can cause problems with everyday life. Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places.

Adults with ADHD often find it hard to concentrate. They often feel restless, impatient and inattentive. They may have difficulty organising their private life and work.

Not all patients with ADHD need to be treated with medicine. For children, the decision to use a medicine must be based on a very thorough assessment of the severity and chronic nature of the child's symptoms.

ADHD does not affect intelligence.

## 2. What you need to know before you take Kiegia XL

**Do not take Kiegia XL if you or your child:**
- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6). If you think you are allergic, ask your doctor for advice
- have a thyroid problem
- take a medicine called 'monoamine oxidase inhibitor' (MAOI) used for depression, or if you took an MAOI in the past 14 days
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- have an eating problem where you do not feel hungry or want to eat (such as anorexia nervosa)
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- have ever had heart problems such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or an inherent heart problem
- have had a problem with the blood vessels in your 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)
  - you have mental health problems such as:
  - a 'psychopathic' or 'borderline personality' problem
  - abnormal thoughts or hallucinations, 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 uninhibited
    - mood changes from depression to mania.

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

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Kiegia XL if you or your child:
- have liver or kidney problems
- develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Focusim XL.
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEG)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs
- are female and have started having periods (see section 'Pregnancy, breast-feeding and fertility' below)
- or any other member of your family have hard-to-control repeated twitching of any parts of the body or you repeat sounds and words (tics)
- have high blood pressure
- have a heart problem which is not mentioned in the section "Do not take Kiegia XL"
- have a mental health problem which is not mentioned in the section "Do not take Kiegia XL". Other mental health problems include:
  - mood swings (from being manic to being depressed – called 'bipolar disorder')
  - starting to be aggressive or hostile, or aggression which 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 applies to you or your child, before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

During treatment, boys and men may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

**Checks that your doctor will make before you or your child start taking methylphenidate**

These checks are to decide if methylphenidate is the correct medicine for you or your child. Your doctor will talk to you about:
- any other medicines you or your child are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you, your child or your family may have
- how you or your child are feeling, such as feeling high or low, having strange thoughts, or if you or your child have 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 behaviour problems you or your child or other family members have or have ever had. Your doctor will discuss whether you or your child are at risk of having mood swings (from being manic to being depressed – called 'bipolar disorder'). Your doctor will check your or your child's mental health history, and check if any of your family has a history of suicide, bipolar disorder or depression

It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you or your child. Your doctor may decide that other medical tests are needed before you or your child start taking this medicine.

**Drug testing/anti-doping testing**

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

**Other medicines and Kiegia XL**

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Do not take methylphenidate if you or your child:
- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in blood pressure (see "Do not take Kiegia XL")

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. It may therefore be necessary to change the dose of the medicine or to discontinue treatment alltogether. If you or your child are taking any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:
- other medicines for depression
- medicines for severe mental health problems (e.g. schizophrenia)
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain substances that can affect blood pressure. It is important to check with your pharmacist when you buy any of these medicines
- medicines that thin the blood to prevent blood clots

Kiegia XL should not be taken together with $H_2$ receptor blockers or antacids which are used to reduce gastric acid secretion or to counteract excessive acitity 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 are taking are included in the list above, ask your doctor or pharmacist for advice before taking methylphenidate.

**Having an operation**

Tell your doctor that you or your child are being treated with Kiegia XL if you or your child is going to have an operation. Methylphenidate should not be taken on the day of surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

**Kiegia XL with food, drink and alcohol**

Taking methylphenidate with food may help to stop stomach pain, nausea and being sick.

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, breast-feeding and fertility**

It is not known if methylphenidate will affect an unborn baby. No effects on fertility have been seen in animal tests.

Ask your doctor or pharmacist for advide before taking this medicine if you or your daughter are:
- sexually active. Your doctor will discuss contraception
- pregnant, may be pregnant or are planning to become pregnant. Your doctor will decide whether you should take methylphenidate
- are breast-feeding or are planning to breast-feed. It is possible that methylphenidate is passed into breast milk. Therefore, your doctor will decide whether you should breast-feed while taking methylphenidate

**Driving and using machines**

You or your child may feel dizzy or sleepy, have problems focussing or have blurred vision, have hallucinations or other side effects of the central nervous system when taking methylphenidate. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

## 3. How to take Kiegia XL

You or your child should always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Dose**

Your doctor will usually start treatment with a low dose and increase it gradually as required.

<u>Children (6 years and over) and adolescents</u>

The recommended starting dose is 20 mg once daily. At the discretion of the doctor, treatment with Kiegia XL can also be started at a dose of 10 mg. The maximum daily dose is 60 mg. Kiegia XL are taken once daily in the morning in patients younger than 18 years of age.

<u>Adults</u>

The maximum daily dose is 80 mg.
- If you take Kiegia XL for the first time, your doctor will start treatment at a dose of 20 mg once daily and, if required, will increase the dose gradually at weekly small increments.
- If you were already treated with a modified-release formulation or any other methylphenidate preparation with a similar release system in childhood and you have just turned 18, your doctor may continue treatment with the same dose. If you were treated with an immediate-release formulation in childhood, your doctor will prescribe the equivalent dose of Kiegia XL

For lower doses or smaller increments different strengths of this medicine and other methylphenidate-containing medicines may be available.

**Things your doctor will do when you or your child is on treatment**
**Your doctor will do some tests:**
- before you or your child starts –to make sure that Kiegia XL is safe and will be of benefit (listed in section "Checks that your doctor will make before you or your child start taking methylphenidate").
- 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 for problems with mood, state of mind or any other unusual feelings, or if these have become worse while taking Kiegia XL

**Method of Administration**

Kiegia XL is for oral use.
- Take Kiegia XL once daily with or without food. Kiegia XL should not be taken too late in the morning as it may cause disturbances in sleep
- The capsule should be swallowed whole, with a drink of water
- Do not crush, chew or divide the capsule or the contents

If you or your child are unable to swallow Kiegia XL you can sprinkle the contents on a small amount of food, as follows:
- Carefully open the capsule and sprinkle the pellets over a small amount of soft food (e.g. apple sauce).
- The food should not be warm because this could affect the special properties of the pellets.
- Do not crush or chew the pellets.
- Immediately eat all of the drug/food mixture.

Do not store any drug/food mixture for future use.

**Long-term treatment**

Kiegia XL should not and does not need to be taken forever. If you or your child takes Kiegia XL for more than one year, your doctor should stop treatment for a short time at least once a year (in children, this may happen during a school holiday). This will show if the medicine is still needed.

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

If you or your child do not feel better, tell your doctor. He may decide that you or your child need a different treatment.

**Not using Kiegia XL properly**

If Kiegia 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 or your child. Do not give this medicine to anyone else, even if their symptoms seem similar.

**If you or your child take more Kiegia XL than you should**

If you or your child have taken too many capsules, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Medical treatment might be needed.

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 forget to take Kiegia XL**

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

**If you or your child stop taking Kiegia XL** If you or your child suddenly stop taking this medicine, the 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 Kiegia XL.

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

**Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Although some people get side effects, most people find that methylphenidate helps them. Your doctor will talk to you about these side effects.

**Some side effects could be serious. If you or your child experience any of the side effects below, see a doctor straight away:**

**Common (may affect up to 1 in 10 people)**
- uneven heartbeat (palpitations)
- mood changes, mood swings or changes in personality

**Uncommon (may affect up to 1 in 100 people)**
- thinking about or feeling like killing yourself
- seeing, feeling, or hearing things that are not real – these are signs of psychosis
- uncontrolled speech and body movements (Tourette's)
- 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 uninhibited (mania)

**Very rare (may affect up to 1 in 10,000 people)**
- 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
- 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 that this side effect is caused by methylphenidate or other medicines that may be taken in combination with methylphenidate

**Not known (frequency cannot be estimated from the available data)**
- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath – these can be signs of heart problems

**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
- feeling sick
- dry mouth

**Common (may affect up to 1 in 10 people)**
- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite
- weight decrease in adults
- panic attack
- decrease in sex drive
- toothache
- itching, rash or raised red itchy rashes (hives)
- excessive sweating
- cough, sore throat or nose and throat irritation, shortness of breath or chest pain
- changes in blood pressure (mainly high blood pressure, fast heart beat (tachycardia), cold hands and feet
- shaking or trembling, feeling dizzy, movements which you cannot control, feeling jittery, being unusually active
- feeling aggressive, agitated, restless, anxious, depressed, stressed, irritable and abnormal behaviour, problems sleeping, tiredness
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst and being sick.
  These side effects usually occur at the start of treatment and can be reduced by taking the medicine with food.

**Uncommon (may affect up to 1 in 100 people)**
- constipation
- chest discomfort
- blood in the urine
- double vision or blurred vision
- muscle pain, muscle twitching, muscle tightness
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings, tension
- dry eye

**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
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

**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
- suicide attempt and suicide, abnormal thinking, lack of feeling or emotion
- fingers and toes feeling numb, tingling and changing colour from white to blue, then red when cold ('Raynaud's phenomenon')
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

**Not known (frequency cannot be estimated from the 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
- severe stomach pain, often with feeling and being sick
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- erectile dysfunction
- excessive uncontrolled talking
- prolonged erections, sometimes painful, or an increased number of erections

**Effects on growth in children**

When used for more than one 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 increase.
- Your doctor will carefully monitor height and weight, as well as how well your child is eating.
- If 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 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.

**How to store Kiegia XL**

Keep this medicine out of the sight and reach of children.
Make sure to store the medicine in a secure place so that nobody else can take it.

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

This medicine does not require any special storage conditions.

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 protect the environment.

## 6. Contents of the pack and other information

**What Kiegia XL contains**
- The active substance is methylphenidate hydrochloride.
  **Kiegia XL 10 mg** modified-release hard capsules contain 8.65 mg methylphenidate as 10 mg methylphenidate hydrochloride.
  **Kiegia XL 20 mg** modified-release hard capsules contain 17.3 mg methylphenidate as 20 mg methylphenidate hydrochloride.
  **Kiegia XL 30 mg** modified-release hard capsules contain 25.95 mg methylphenidate as 30 mg methylphenidate hydrochloride.
  **Kiegia XL 40 mg** modified-release hard capsules contain 34.6 mg methylphenidate as 40 mg methylphenidate hydrochloride.
  Kiegia XL 60 mg modified-release hard capsules contain 51.9 mg methylphenidate as 60 mg methylphenidate hydrochloride.
- The other excipients are:
  *Capsule contents:* cellulose, microcrystalline, hypromellose, talc, methacrylic acid-methyl methacrylate copolymer (1:1), triethyl citrate, ethylcellulose, hydroxypropylcellulose
  *Capsule shell:* gelatin, titanium dioxide (E171)

Additionally in Kiegia XL10 mg, 30 mg, 40 mg and 60 mg modified-release hard capsules contian: Iron oxide yellow (E172)

*Printed ink*
Shellac glaze
Iron oxide black (E172)
Propylene glycol

**What Kiegia XL looks like and contents of the pack**

Modified-release hard capsules

<u>**Kiegia XL 10 mg** modified-release hard capsules</u>
Opaque hard gelatine capsule (size 3) with orange cap and white body imprinted "10" with black ink, filled with white to off-white spherical pellets. Capsule length: 15.9 mm.

<u>**Kiegia XL 20 mg** modified-release hard capsules</u>
Opaque hard gelatine capsule (size 3) with white cap and white body, imprinted "20" with black ink, filled with white to off-white spherical pellets. Capsule length: 15.9 mm.

<u>**Kiegia XL 30 mg** modified-release hard capsules</u>
Opaque hard gelatine capsule (size 2) with yellow cap and yellow body, imprinted "30" with black ink, filled with white to off-white spherical pellets. Capsule length: 18 mm.

<u>**Kiegia XL 40 mg** modified-release hard capsules</u>
Opaque hard gelatine capsule (size 1) with orange cap and orange body, imprinted "40" with black ink, filled with white to off-white spherical pellets. Capsule length: 19.4 mm.

<u>**Kiegia XL 60 mg** modified-release hard capsules</u>
Opaque hard gelatine capsule (size 0) with yellow cap and white body imprinted "60" with black ink, filled with white to off-white spherical pellets. Capsule length: 21.7 mm.

Kiegia XL 10 mg/20 mg/30 mg/40 mg /60 mg modified-release hard capsules are available in:

HDPE bottles with child-resistant closure (PP)
28, 30, 40, 50, 56, 60, 84, 100 modified-release hard capsules

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Strides Pharma UK Limited
Unit 4, The Metro Centre
Dwight Road, Watford
WD18 9SS
United Kingdom

**Manufacturer**
Konapharma AG
Netzibodenstrasse 23d
4133 Pratteln
Switzerland

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**This leaflet was last revised in 09/2025.**

160 x 600 mm Front Side

160 x 600 mm Back Side

SPUK
Konapharma AG
Pack insert