

**PATIENT INFORMATION LEAFLET**  
**Medikinet® XL 5 mg modified-release capsules, hard**  
(methylphenidate hydrochloride)

▼ 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.

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 XL

#### Do not take Medikinet XL 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 XL'
- 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)

Do not take methylphenidate 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 methylphenidate can make these problems worse.

#### Warnings and precautions

Talk to your doctor before taking Medikinet XL if you or your child

- has liver or kidney problems
- has problems with swallowing or swallowing whole tablets
- 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 (tics)
- 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. Methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child. During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time.

#### 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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 out of the sight and reach of children.**
- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the blister label and outer carton after EXP. The expiry date refers to the last day of that month.
- If your doctor tells you to stop taking this medicine, take any remaining medicine back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- If your medicine becomes discoloured or shows any other signs of deterioration, ask your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Medikinet XL contains

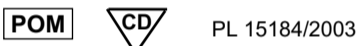
- Each modified-release capsule, hard contains 5mg methylphenidate hydrochloride, equivalent to 4.35mg methylphenidate.
- The other ingredients are: sugar spheres (containing sucrose and maize starch), methacrylic acid - ethyl acrylate copolymer (1:1), talc, triethyl citrate, polyvinyl alcohol, macrogol 3350, polysorbate 80, sodium hydroxide, sodium lauryl sulfate, simethicone, colloidal anhydrous silica, methylcellulose, sorbic acid, indigo carmine, aluminium lake (E132).
- **The capsule shell:** gelatin, titanium dioxide (E171), sodium lauryl sulfate, purified water.

#### What Medikinet XL looks like and contents of the pack

- Medikinet XL has a white opaque capsule body/white opaque capsule cap (15.9 mm) containing white and blue pellets.
- Each pack contains 30 modified-release capsules, hard.

#### Manufacturer and Licence Holder

This medicine is manufactured by MEDICE Arzneimittel Pütter GmbH & Co. KG, Kuhlweg 37, 58638 Iserlohn, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.



Medikinet XL 5mg modified-release capsules, hard

Medikinet XL is a registered trademark of Medice Arzneimittel Pütter GmbH & Co. KG .

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## Blind or partially sighted? Is this leaflet hard to see or read? Phone Lexon (UK) Limited, Tel: 01527 505414 to obtain the leaflet in a format suitable for you

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

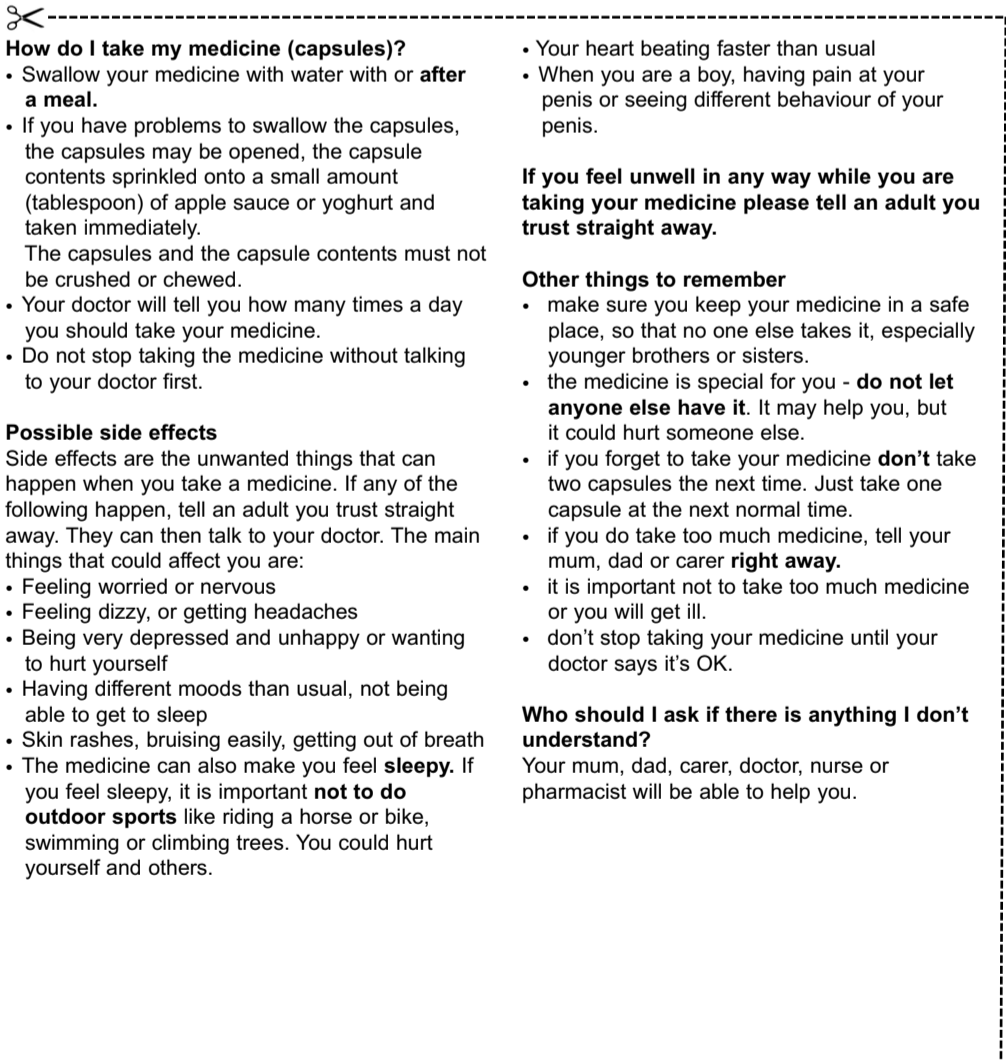
**If you feel unwell in any way while you are taking your medicine please tell an adult you trust straight away.**

#### 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.



#### 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 apple sauce 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 headaches
- 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.

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 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 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 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. For adult patients that are new to Medikinet XL, your doctor may refer you to a heart specialist.

#### Drug testing

This medicine 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 XL

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 methylphenidate 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 methylphenidate may cause a sudden increase in blood pressure.

If you or your child is taking other medicines, methylphenidate 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 XL 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 methylphenidate.

#### Having an operation

Tell your doctor 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.

#### Taking methylphenidate 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

Available data do not suggest an increased risk of overall birth defects, whilst a small increase in the risk of malformations of the heart when used during the first three months of pregnancy could not be ruled out. Your doctor will be able to give you more information about this risk. Tell your doctor or pharmacist before using methylphenidate if you or your daughter:

- is having sex. Your doctor will discuss contraception.
- is pregnant or think she might be pregnant. Your doctor will decide whether methylphenidate should be taken.
- is breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk. Therefore, your doctor will decide whether you or your daughter should breast-feed while taking methylphenidate.

#### Driving and using machines

You or your child may feel dizzy, feel drowsy, have problems focussing or have blurred vision, have hallucinations or other side effects in 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. This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.

- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

#### Medikinet XL contains sucrose

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

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

### 3. HOW TO TAKE MEDIKINET XL

You or your child should always take Medikinet XL 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 XL 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 XL before

- if you have already taken Medikinet XL 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 XL 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 XL 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 XL.

#### 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 (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 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).

#### Information for children and young people

This info is to help you learn the main things about your medicine called Medikinet XL. If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.

It may help if you read small bits at a time.

#### Why have I been given this medicine?

This medicine can help children and young people with 'ADHD'.

- ADHD can make you:
  - run about too much
  - not be able to pay attention
  - act quickly without thinking about what will happen next (impulsive).
- It affects learning, making friends and how you think about yourself. It is not your fault.

#### While you are taking this medicine

- as well as taking this medicine you will also get help with ways to you cope with your ADHD such as talking to ADHD specialists.
- this medicine should help you. But it does not cure ADHD.
- you will need to go to your doctor several times a year for check ups. This is to make sure the medicine is working and that you are growing and developing OK.

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, chest pain, 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

>>> please turn over

