Package Leaflet: Information for the user

Atenza XL 18 mg prolonged release tablets
Atenza XL 27 mg prolonged release tablets
Atenza XL 36 mg prolonged release tablets
Atenza XL 54 mg prolonged release tablets

methylphenidate hydrochloride

Read all of this leaflet carefully before you or your child starts 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 **Atenza XL** is and what it is used for
2. What you need to know before you take **Atenza XL**
3. How to take **Atenza XL**
4. Possible side effects
5. How to store **Atenza XL**
6. Contents of the pack and other information

1. What Atenza XL is and what it is used for

What it is used for
Atenza XL is used to treat 'attention deficit hyperactivity disorder' (ADHD).
- It is used in children aged 6 years and over and in adults.
- It is used only after trying treatments which do not involve medicines, such as counselling and behavioural therapy.

Atenza XL is not for use as a treatment for ADHD in children under 6 years.

How it works
Atenza XL improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes:
- psychological
- educational and
- social therapy.

It is prescribed only by doctors who have experience in children , adolescents or adults with behaviour problems. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had 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
- to concentrate.

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

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

ADHD does not affect the intelligence.

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.

2. What you need to know before you take Atenza XL

Do not take Atenza XL if you or your child:
- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- have a thyroid problem
- have increased pressure in the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- have an eating problem when 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 were born with a 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)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor)- see 'Other medicines and Atenza XL'
- have 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.

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

Warnings and precautions
Talk to your doctor before taking Atenza XL if you or your child:
- have liver or kidney problems

- have problems swallowing or swallowing whole tablets
- have a narrowing or blockage of the gut or food-pipe
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs
- are a girl and have started your periods (see the 'Pregnancy, breast-feeding and contraception' section below)
- have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- have high blood pressure
- have a heart problem which is not in the 'Do not take' section above
- have a mental health problem which is not in the 'Do not take' section above
- develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Atenza XL.

Other mental health problems include:

- mood swings (from being manic to being depressed - called 'bipolar disorder')
- feeling aggressive or hostile
- 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 before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you.

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.

Checks that your doctor will make before you start taking Atenza XL

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 are 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 are feeling, such as feeling high or low, having strange thoughts or if you 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 other family members have ever had. Your doctor will discuss whether you are at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check your 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. Your doctor may decide that other medical tests are needed before you start taking this medicine. For adult patients that are new to Atenza XL, your doctor may refer you to a heart specialist.

Other medicines and Atenza XL

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

Do not take methylphenidate if you:

- 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 your blood pressure (see "Do not take Atenza XL").

Tell your doctor or pharmacist if you are taking any of the following medicines for depression or anxiety:

- tricyclic antidepressant
- selective serotonin reuptake inhibitor (SSRI)
- serotonin and norepinephrine reuptake inhibitor' (SNRI).

Taking methylphenidate with these types of medicine could cause a life-threatening increase of 'serotonin' in the brain (serotonin syndrome), which may lead to feeling confused or restless, sweating, shivering, muscle jerks or fast heart beat. If you develop these side effects, see a doctor straight away.

If you are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you are taking any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:

- medicines for severe mental health problems
- medicines for Parkinson's disease (such as levodopa)
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which 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.

If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

Please tell you doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Having an operation

Tell your doctor if you are 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.

Drug testing

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

Atenza XL 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, breast-feeding and contraception

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 are

- having sex. Your doctor will discuss contraception with you
- pregnant or think you may be pregnant. Your doctor will decide whether you should take methylphenidate.
- breast-feeding or planning to breast-feed. Methylphenidate passes into breast milk.

Therefore, your doctor will decide whether you should breast-feed while taking methylphenidate.

Driving and using machines
You may feel dizzy, have problems focussing or have blurred vision 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. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected.

Atenza XL contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Atenza XL

How much to take
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- your doctor will usually start treatment with a low dose and increase. The daily dose by 18 mg no sooner than once a week if necessary. The aim should be the lowest dose that is effective for you. Your doctor will decide the maximum daily dose for you or your child.
- you should take Atenza XL once each day in the morning with a glass of water.

The tablet should be swallowed whole and not chewed, broken, or crushed. The tablet may be taken with or without food.
The tablet does not dissolve completely after all of the drug has been released and sometimes the tablet shell may appear in the stools. This is normal.

Use in children 6 years and over

- the recommended starting dose of Atenza XL is 18 mg once daily for children who are not currently taking methylphenidate, or for children who are switching from another stimulant to methylphenidate,
- the maximum daily dose is 54 mg.

Use in adults
For adults who have taken Atenza XL before:

- if you have already taken Atenza 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.

For adults who have not taken Atenza XL before:

- the recommended starting dose is 18 mg daily.
- The maximum daily dose in adults is 72 mg.

If you do 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. They may decide a different treatment is needed.

Not using Atenza XL properly
If Atenza XL is not used properly, this may cause abnormal behaviour. It may also mean that you start to depend on the medicine. Tell your doctor if you have 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 take more Atenza XL than you should
If you take too much medicine, 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 forget to take Atenza XL
Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

If you stop taking Atenza 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 Atenza XL.

Things your doctor will do when you are on treatment
Your doctor will do some tests
- before you start - to make sure that Atenza XL is safe and will be of benefit.
- after you start - 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 your appetite
  - measuring height and weight
  - measuring blood pressure and heart rate
  - checking whether you have any problems with your mood, state of mind or any other unusual feelings. Or if these have got worse while taking Atenza XL.

Long-term treatment
Atenza XL does not need to be taken for ever. If you take Atenza XL for more than a year, your doctor should stop treatment for a short time, this may happen during a school holiday. This will show if the medicine is still needed.

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

4. 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 have 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 or 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 un-inhibited (mania).

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

- heart attack
- sudden death
- suicidal attempt
- fits (seizures, convulsions epilepsy)
- skin peeling or purplish red patches
- inflammation or blocked arteries in the brain
- temporary paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain)
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system
- 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 medicinal products 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)
- prolonged erections, sometimes painful or an increased number of erections.

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)

- headache
- feeling nervous
- not being able to sleep.

Common (may affect up to 1 in 10 people)

- joint pain

- blurred vision
- tension headache
- dry mouth, thirst
- trouble falling asleep
- high temperature (fever)
- decreased sex drive
- unusual hair loss or thinning
- muscle tightness, muscle cramps
- loss of appetite or decreased appetite
- inability to develop or maintain an erection
- itching, rash or raised red itchy rashes (hives)
- feeling unusually sleepy or drowsy, feeling tired
- excessive teeth grinding (bruxism)
- feeling of panic
- tingling feeling, prickling, or numbness of the skin
- increased alanine aminotransferase (liver enzyme) level in your blood
- cough, sore throat or nose and throat irritation; upper respiratory tract infection; sinus infection
- high blood pressure, fast heart beat (tachycardia)
- dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour
- upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.
- excessive sweating
- weight decreased.

Uncommon (may affect up to 1 in 100 people)

- dry eyes
- constipation
- chest discomfort
- blood in the urine
- listlessness
- shaking or trembling
- increased need to pass urine
- muscle pain, muscle twitching
- shortness of breath or chest pain
- feeling hot
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping.

Rare (may affect up to 1 in 1,000 people)

- problems with sex drive
- feeling disorientated or confused
- trouble seeing or double vision
- 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)

- muscle cramps
- small red marks on the skin
- abnormal liver function including sudden liver failure and coma
- changes in test results – including liver and blood tests
- 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').

Not known (frequency cannot be estimated from the available data)

- migraine
- dilated pupils
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true
- severe stomach pain, often with feeling and being sick
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering
- nosebleed
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma).

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 growth.
- your doctor will carefully watch your height and weight, as well as how well you are eating.
- if you are not growing as expected, then your 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 Atenza 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 label. The expiry date refers to the last day of that month.
Keep the bottle tightly closed in order to protect from moisture.
This medicine does not require any special temperature 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 to protect the environment.

6. Contents of the pack and other information

What Atenza XL contains
The active substance is methylphenidate hydrochloride

- Each tablet contains 18 mg, 27 mg, 36 mg or 54 mg of methylphenidate hydrochloride.

The other ingredients are:

- *Tablet core:* hypromellose, macrogol, succinic acid, magnesium stearate, sodium chloride, silica colloidal anhydrous, black iron oxide (E172).
- *Film coating:* cellullose acetate, macrogol.
- *Clear coating:* hypromellose, macrogol, phosphoric acid (for pH adjustments).
- *Colour coating:* lactose monohydrate, hypromellose, triacetin, titanium dioxide (E171), yellow iron oxide (E172) (18 mg), red iron oxide, (E172) (18mg, 27mg, 54mg), black iron oxide (E172) (27mg).

What Atenza XL looks like and contents of the pack

- 18 mg: Round, biconvex, yellow film-coated tablets of approximately 9 mm of diameter with a small hole in one side of the tablet.
- 27 mg: Round, biconvex, grey film-coated tablets of approximately 9 mm of diameter with a small hole in one side of the tablet.
- 36 mg: Round, biconvex, white film-coated tablets of approximately 10 mm of diameter with a small hole in one side of the tablet.
- 54 mg: Round, biconvex, pink film-coated tablets of approximately 10 mm of diameter with a small hole in one side of the tablet

The medicinal product is available in a plastic bottle, including 2 desiccant canisters, with plastic child resistant cap. The desiccant canisters are used to keep the tablets dry and should not be eaten.

Pack sizes are: 30 tablets; 60 tablets (2x30) and 90 tablets (3x30).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Exeltis Healthcare, S.L.
Avenida Miralcampo, 7
Polígono Industrial Miralcampo
19200, Azuqueca de Henares
Guadalajara, Spain

Laboratorios Liconsa, S.A.
Calle Dulcinea S/n. Alcalá De Henares.
28805 – Madrid
Spain

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