

Approved Patient Information Leaflet for Medicines for Human Use:

ATEROCON LA

SCHEDULING STATUS

S6

ATEROCON LA 10 mg modified-release hard capsules

ATEROCON LA 20 mg modified-release hard capsules

ATEROCON LA 30 mg modified-release hard capsules

ATEROCON LA 40 mg modified-release hard capsules

ATEROCON LA 60 mg modified-release hard capsules

Methylphenidate hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking ATEROCON LA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ATEROCON LA has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ATEROCON LA is and what it is used for
2. What you need to know before you take ATEROCON LA
3. How to take ATEROCON LA
4. Possible side effects
5. How to store ATEROCON LA
6. Contents of the pack and other information

1. What ATEROCON LA is and what it is used for

ATEROCON LA contains the active substance methylphenidate.

ATEROCON LA is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).

- It is used in children and young people between the ages of 6 and 18, and in adults.
- It is used only after trying treatments which do not involve medicines, such as counselling and behavioural therapy and which have been insufficient.

ATEROCON LA is not for use as a treatment for ADHD in children under 6 years of age or for initiation of treatment in adults. When treatment was started at a younger age, it might be appropriate to continue taking ATEROCON LA when you become an adult.

Your doctor will advise you about this. It is not known if it is safe or of benefit in children under 6 years of age.

How it works

ATEROCON LA 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.

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ATEROCON LA is prescribed only by specialist doctors who have experience in children, young people's and adults' behavioural problems. This specialist will follow up your or your child's further treatment. A thorough examination is necessary. 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, using treatment programmes as well as medicine helps to manage ADHD.

Examinations during treatment with ATEROCON LA

Your doctor will regularly check your or your child's health while you or your child are treated with ATEROCON LA (Please read carefully section 3, "Things your doctor will do when you or your child are on treatment").

2. What you need to know before you or your child take ATEROCON LA

Do not take ATEROCON LA if you or your child:

- are allergic (hypersensitive) to methylphenidate, or any of the other ingredients of ATEROCON LA (listed in section 6)
- have a thyroid problem
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor (MAOI))- see 'Other medicines and ATEROCON LA
- have 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 (caused by a burst blood vessel or blocked blood supply to the brain), swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- have mental health problems such as:
 - an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
 - 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 uninhibited
- mood changes from depression to mania.
- have significant anxiety, tension, and agitation because ATEROCON LA may make these symptoms worse.
- have a family history or have been diagnosed with Tourette's syndrome (a neurological problem characterised by hard to control and repeated twitching or utterance of sound and words, often swear words).
- are pregnant and or breastfeeding

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 you take methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

Talk to your doctor before taking ATEROCON LA if you or your child:

- have liver or kidney problems
- 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
- 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 ATEROCON LA' section above
- have a mental health problem which is not in the 'Do not take ATEROCON LA' 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 your aggression gets worse

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- 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.

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 or your family may have
- how you or your child 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 your child or other family members 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'). 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 start taking this medicine.

While taking ATEROCON LA

- 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.

Other medicines and ATEROCON LA

Always tell your healthcare professional if you or your child are taking any other medicine. (This includes complementary or traditional 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 your blood pressure.

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. 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
- medicines for epilepsy
- medicines used to reduce or increase blood pressure

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- 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
- H2-receptor blockers or antacids which are used to reduce gastric acid secretion or to counteract excessive acidity in the stomach, as this could lead to a change in the release of the total amount of active substance when taken together with ATEROCON LA.

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 before taking methylphenidate.

Having an operation

Tell your doctor if you are going to have an operation. You should not take methylphenidate on the day of your 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.

ATEROCON LA with alcohol

Do not drink alcohol while taking ATEROCON LA. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ATEROCON LA.

Tell your doctor or pharmacist before using methylphenidate if you or your daughter are:

- sexually active. Your doctor will discuss contraception
- pregnant or may be pregnant.
- breastfeeding or planning to breastfeed. It is possible that methylphenidate is passed into human breast milk.

Driving and using machines

The ability to drive a motor vehicle or operate machinery may be impaired by ATEROCON LA capsules. You or your child 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. Before driving or operating potentially dangerous machinery, determine how this medicine affects you or your child.

3. How to take ATEROCON LA

Do not share medicine prescribed for you or your child with any other person, even if their symptoms seem similar.

Always take ATEROCON LA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose:

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

Children (older than 6 years) and adolescents:

- the maximum daily dose is 60 mg. ATEROCON LA is taken once daily in the morning in patients younger than 18.

Adults:

- the maximum daily dose is 80 mg for adults.
- If you have not taken ATEROCON LA before, your doctor will start your treatment with 20 mg, and will increase the dose gradually if required.
- If you have been treated with ATEROCON LA for ADHD during childhood, and have recently turned 18 years of age, your doctor can continue to prescribe the same dose. If you have been treated with immediate release methylphenidate tablets during childhood, your doctor will prescribe the equivalent dose of ATEROCON LA
- ATEROCON LA is taken once daily usually in the morning with or without food in adults. Do not take your medicine too late in the day, in order to prevent sleep disturbance.

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

Things your doctor will do when you or your child are on treatment

Your doctor will do some tests:

- Before you or your child start - to make sure that ATEROCON LA is safe and will be of benefit.
- After you or your child 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 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 ATEROCON LA.

Method of administration

ATEROCON LA is for oral use.

- Take ATEROCON LA once daily with or without food. ATEROCON LA 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 ATEROCON LA, you can sprinkle the contents on a small amount of food, as follows:

- Carefully open the capsule and sprinkle the beads 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 beads

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- Immediately eat all of the medicine/food mixture

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

If you have the impression that the effect of ATEROCON LA is too strong or too weak, tell your doctor or pharmacist.

Long-term treatment

ATEROCON LA does not need to be taken forever. If you or your child take ATEROCON LA for more than a year, your doctor should stop treatment at least once per year for a short time. For 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. They may decide you or your child need a different treatment.

Not using ATEROCON LA properly

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

If you or your child take more ATEROCON LA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the medicine pack with you. This is so the doctor knows what you or your child have taken.

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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, dry nose and mouth and a serious syndrome called rhabdomyolysis due to a direct or indirect muscle injury that results from the death of muscle fibres and release of their contents into the bloodstream which can lead to serious complications such as renal (kidney) failure.

If you or your child forget to take a dose of ATEROCON LA

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

If you or your child stop taking ATEROCON LA

If you or your child suddenly stop taking ATEROCON LA, 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 ATEROCON LA.

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

4. Possible side effects

ATEROCON LA can have side effects.

Not all side effects reported for ATEROCON LA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ATEROCON LA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop ATEROCON LA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe sudden allergic reactions (e.g., rash, itching, hives, swelling of the face, lips, tongue, throat, and airways (breathing tubes), shortness of breath, wheezing or difficulty breathing (see section 2: Warnings and precautions)
- heart attack (also see section 2: Warnings and precautions)
- fits or seizure (also see section 2: Warnings and precautions)
- sudden death
- redness and peeling of the skin over large areas of the body (exfoliative dermatitis)
- 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.
- prolonged erections, sometimes painful, or an increased number of erections (see section 2: Warnings and precautions)
- thinking about or feeling like killing yourself or suicidal attempt

These are very serious side effects. If you have them, you may have had a serious reaction to ATEROCON LA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- uneven heartbeat (palpitations) or unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems) (see section 2: Warnings)

Less frequent side effects:

- chest pain or severe chest pain, often also spreading to the shoulders, arms, and neck, shortness of breath or unexplained fainting shortness of breath (these can be signs of heart problems) (these can be signs of heart problems)
- inflammation or blocked arteries in the brain
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system (tics)
- uncontrolled speech and body movements (Tourette's)
- feeling, seeing or hearing things that are not real, these are signs of psychosis
- feeling unusually excited, over-active and un-inhibited (mania)
- 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
- abnormal liver function including sudden liver failure and coma

Side effects with frequency unknown:

- a disease that affects your brain and behaviour and lead to an inability to control the use of this medicine (dependence)
- a major fit ('grand mal convulsions')
- temporary paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels of the brain ([e.g. stroke, cerebral arteritis or cerebral occlusion])

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased appetite, moderately reduced weight and height gain
- headache
- feeling nervous, tension, mood swings
- not being able to sleep
- feeling sick
- dry mouth
- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- panic attack
- decrease in sex drive
- excessive teeth grinding (bruxism)
- itching, rash or raised red itchy rashes (hives)
- excessive sweating
- cough, sore throat or nose and throat irritation, shortness of breath or chest pain
- high blood pressure, fast heartbeat (tachycardia)
- shaking or trembling, feeling dizzy, movements which you cannot control, feeling jittery, being unusually active
- tension headache
- feeling pins and needles
- feeling aggressive, agitated, restless, anxious, depressed, stressed, irritable and abnormal behaviour, problems sleeping, tiredness
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst and being sick

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- vertigo (feeling dizzy; nausea)
- shortness of breath

Less frequent side effects:

- cold hands and feet
- constipation
- blood in the urine, frequent urination
- double vision or blurred vision, dry eyes
- muscle pain, muscle twitching, muscle tightness
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings
- mood changes or changes in personality
- changes in sex drive
- feeling disorientated
- swelling of the breasts in men
- abnormal menstruation
- redness of the skin, red raised skin rash
- small red marks on the skin
- abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- muscle cramps
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon')
- excessive uncontrolled talking
- upset stomach
- hot flushes

Side effects with frequency unknown (frequency cannot be estimated from the available data):

- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- inability to control the excretion of urine (incontinence)
- migraine, continuous long-term depression
- chest discomfort
- slow, fast or extra heart beats
- very high fever
- unwanted thoughts that keep coming back
- believing things that are not true, confusion
- dilated pupils, trouble seeing, pain in the eye
- ringing in ears

Effects on growth

When used for more than a year, methylphenidate may cause reduced growth in some 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ATEROCON LA.

5. How to store ATEROCON LA

Store all medicines out of reach of children.

- Store at or below 25 °C in a dry place.
- Store in original package.
- Keep container tightly closed.
- Protect from moisture.
- Do not store in a bathroom
- Do not use after the expiry date stated on the blister or carton. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ATEROCON LA contains

The active ingredient is methylphenidate.

ATEROCON LA 10 mg modified-release hard capsules

Each modified-release capsule contains 8,65 mg methylphenidate as 10 mg methylphenidate hydrochloride.

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ATEROCON LA 20 mg modified-release hard capsules

Each modified-release capsule contains 17,3 mg methylphenidate as 20 mg methylphenidate hydrochloride.

ATEROCON LA 30 mg modified-release hard capsules

Each modified-release capsule contains 25,95 mg methylphenidate as 30 mg methylphenidate hydrochloride.

ATEROCON LA 40 mg modified-release hard capsules

Each modified-release capsule contains 34,6 mg methylphenidate as 40 mg methylphenidate hydrochloride.

ATEROCON LA 60 mg modified-release hard capsules

Each modified-release capsule contains 51,9 mg methylphenidate as 60 mg methylphenidate hydrochloride.

The other ingredients are:

Capsule contents

Ethylcellulose

Hydroxypropylcellulose

Hypromellose

Methacrylic acid-methyl methacrylate copolymer (1:1)

Microcrystalline cellulose

Talc

Triethyl citrate

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Capsule shell

Gelatin

Titanium dioxide (E171)

Additionally, in ATEROCON LA 10 mg modified-release hard capsules, ATEROCON LA 30 mg modified-release hard capsules, ATEROCON LA 40 mg modified-release hard capsules and ATEROCON LA 60 mg modified-release hard capsules:

Iron oxide yellow (E172)

Printed ink

Iron oxide black (E172)

Propylene glycol

Shellac glaze

What ATEROCON LA looks like and contents of the pack

ATEROCON LA 10 mg modified-release hard capsules

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.

ATEROCON LA 20 mg modified-release hard capsules

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.

ATEROCON LA 30 mg modified-release hard capsules

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.

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ATEROCON LA 40 mg modified-release hard capsules

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.

ATEROCON LA 60 mg modified-release hard capsules

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.

ATEROCON LA 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, 56, 60, 84, 100 modified-release hard capsules

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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ATEROCON LA 20 mg modified-release hard capsules: 54/1.2/0432

ATEROCON LA 30 mg modified-release hard capsules: 54/1.2/0433

ATEROCON LA 40 mg modified-release hard capsules: 54/1.2/0434

ATEROCON LA 60 mg modified-release hard capsules: 54/1.2/0435

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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