

Package Leaflet: Information for the user

Ritalin® LA, 20 30 40 mg prolonged-release capsules
Methylphenidate

The name of your medicine is Ritalin LA. It contains the active substance ‘methylphenidate hydrochloride’. The name ‘methylphenidate’ will also be used in this leaflet.

Read all of this leaflet carefully before you or your child starts taking this medicine.

- 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 or your child. Do not pass it on to others. It may harm them, even if they have the same symptoms.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

What it is used for

Ritalin 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.

Ritalin LA 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 children under 6 years of age. .

How it works

Ritalin 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.

Ritalin LA is prescribed only by a specialist in behavioural disorders. This specialist will follow up your 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. Using treatment programmes as well as medicine helps to manage ADHD.

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.

Many children and young people struggle to do these things. However, with ADHD they 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.

ADHD does not affect intelligence.

Examinations during treatment with Ritalin LA

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

2. Before you or your child take methylphenidate

Do not take methylphenidate if you or your child:

- are allergic (hypersensitive) to methylphenidate or any of the other ingredients of Ritalin LA (listed in Section 6)
- have a thyroid problem
- have increased pressure in your eye (glaucoma)
- have a tumour of your 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)
- have mental health problems such as:
 - o a ‘psychopathic’ or ‘borderline personality’ problem
 - o abnormal thoughts or visions or an illness called ‘schizophrenia’
 - o 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 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.

Check with your doctor or pharmacist before treatment 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
- are female and have started having 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. Other mental health problems include:
 - o mood swings (from being manic to being depressed - called ‘bipolar disorder’)
 - o starting to be aggressive or hostile, or your 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. 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 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.

Warnings and precautions

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.

Taking other medicines

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

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
- 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 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 or your child 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.

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, breast-feeding and fertility

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 are:

- having sex. Your doctor will discuss contraception
- pregnant or may be pregnant. Your doctor will decide whether you should take methylphenidate.
- 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 should breast-feed while taking methylphenidate.

Driving or using machines

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.

Important information about some of the ingredients of Ritalin LA

Sugar spheres(Sucrose)

This medicine contains sucrose (a type of sugar). If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ritalin LA

How much to take

Always take Ritalin LA 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 it gradually as required.
 - o Children/adolescents: the maximum daily dose is 60 mg. Ritalin LA is taken once daily in the morning in patients younger than 18.
 - o Adults: the maximum daily dose is 80 mg for adults.
 - If you have not taken Ritalin LA before, your doctor will start your treatment with 20mg, and will increase the dose gradually if required.
 - If you have been treated with Ritalin 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 Ritalin tablets during childhood,

- your doctor will prescribe the equivalent dose of Ritalin LA
- Ritalin 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
- take Ritalin LA with or without food.
- 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 Ritalin 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
- Immediately eat all of the drug/food mixture

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

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 Ritalin LA properly

If Ritalin 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.

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 Ritalin LA than you should

If you or your child take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken.

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 rhabdomyolysis.

If you or your child forget to take Ritalin LA

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 Ritalin LA

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 Ritalin LA.

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 Ritalin 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 Ritalin LA.

Long-term treatment

Ritalin LA does not need to be taken for ever. If you or your child take Ritalin 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, methylphenidate can cause side effects, but 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 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
- excessive teeth grinding (bruxism)

Uncommon (may affect up to 1 in 100 people)

- 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)
- 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, 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 drugs 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.
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering

If you or your child 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
- 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
- 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
- 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 .

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.

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

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

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- abnormal liver function including liver failure and coma
- changes in test results – including liver and blood tests
- suicidal attempt, abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- 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
- 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)
- excessive uncontrolled talking
- nosebleed

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.

If any of the side effects worry you, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ritalin LA

Keep out of the reach and sight of children.

Do not use Ritalin LA after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C.

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. Further information

What Ritalin LA contains

The active substance is methylphenidate hydrochloride

- Ritalin LA 20 mg contains 20 mg of methylphenidate hydrochloride.
- Ritalin LA 30 mg contains 30 mg of methylphenidate hydrochloride.
- Ritalin LA 40 mg contains 40 mg of methylphenidate hydrochloride.

The other ingredients are:

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ammonio methacrylate copolymer, gelatine, methacrylic acid copolymer, sugar spheres, talc, titanium dioxide (E171), triethyl citrate, yellow iron oxide (E172) (30 and 40mg capsules only), black iron oxide (E172) (40mg capsules only), macrogol, red iron oxide (E172) (40mg capsules only).

What Ritalin LA looks like and contents of the pack

Ritalin LA Prolonged Release capsules are available in three strengths: 20 mg, 30 mg and 40 mg. The medicinal product is available in bottles containing 30 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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