

Ritalin LA®

Methylphenidate hydrochloride

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Ritalin LA?

Ritalin LA contains the active ingredient Methylphenidate hydrochloride. Ritalin LA is used to treat Attention-Deficit Hyperactivity Disorder (ADHD).

For more information, see Section [1. Why am I using Ritalin LA?](#) in the full CMI.

2. What should I know before I use Ritalin LA?

Do not use if you have ever had an allergic reaction to Ritalin LA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ritalin LA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ritalin LA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ritalin LA?

- Your doctor will advise you of the appropriate dose.
- Take Ritalin LA orally once daily in the morning with or without food.
- Take the medicine exactly as prescribed by your doctor.

More instructions can be found in Section [4. How do I use Ritalin LA?](#) in the full CMI.

5. What should I know while using Ritalin LA?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist

	<p>you visit that you are using Ritalin LA.</p> <ul style="list-style-type: none"> • Tell your doctor immediately if you become pregnant while on Ritalin LA. • Contact your doctor immediately if you have any abnormal thoughts, suicidal thoughts, over-active/ excited or uninhibited actions, aggressive behaviour or seeing things (hallucinations).
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not change the dose without speaking to your doctor first.
Driving or using machines	<ul style="list-style-type: none"> • Ritalin LA may cause dizziness, drowsiness, blurred vision, or hallucinations (seeing or hearing things that aren't there) in some people. Be careful before you drive or use any machines or tools or ride a bike until you

	know how Ritalin LA affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Alcohol may make the side effects worse. • Check to make sure food and other medicines taken do not contain alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 30°C. • Keep your tablets out of reach of children.

For more information, see Section [5. What should I know while using Ritalin LA?](#) in the full CMI.

6. Are there any side effects?

Common side effects include blurred vision, drowsiness, fatigue, mood changes, vomiting, rash, joint pain, depression, anxiety, nervousness, agitation, aggression.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: DRUG DEPENDENCE: Ritalin LA should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow up.

Ritalin LA®

Active ingredient(s): *Methylphenidate hydrochloride.*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ritalin LA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ritalin LA.**

Where to find information in this leaflet:

- [1. Why am I taking Ritalin LA?](#)
- [2. What should I know before I take Ritalin LA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ritalin LA?](#)

[5. What should I know while using Ritalin LA?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I taking Ritalin LA?

Ritalin LA contains the active ingredient Methylphenidate hydrochloride. Ritalin LA is a class of medicine that increases the activity of the brain.

Ritalin LA is used to treat Attention-Deficit Hyperactivity Disorder (ADHD).

2. What should I know before I take Ritalin LA?

Warnings

Do not use Ritalin LA if:

- you are allergic to Methylphenidate hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you have anxiety, tension or agitation
- you have Tourette's Syndrome (uncontrolled speech, body movements or tics) or a family history of Tourette's
- you have Glaucoma (increased pressure in the eye)
- you have an overactive thyroid or other thyroid problems

- you have heart problems - heart attack, irregular heartbeat, chest pain (angina), heart failure, heart disease or if you were born with a heart problem
- you have very high blood pressure (hypertension) or narrowing of the blood vessels (arterial occlusive disease, which can cause pain in the arms and legs)
- you have severe depression, an eating disorder (anorexia) or other mental illness
- you have a tumour in the adrenal gland which can cause high blood pressure and headaches.

Do not use Ritalin LA in known drug dependence or alcohol abuse cases.

Ritalin LA should not be taken on the day of surgery with anesthetics due to an increased risk of blood pressure.

Check with your doctor if you:

- have any other medical conditions such as depression, suicidal thoughts or behaviour, seeing or feeling things that are not there (hallucinations), unusual active or depressed mood (bipolar illness), aggressive behaviour
- have abnormal thoughts or are over-excited, over-active or un-inhibited
- have motor or verbal tics, uncontrolled speech or movements, repeated twitching or make repeated sounds or words, or if a family member has any of these
- have had fits/convulsions

- experience all of these problems: restlessness, tremor, sudden muscle contractions, abnormal high temperature, nausea, vomiting
- have high blood pressure (headaches, blurred vision, chest pain)
- have any other medical conditions such as current or previous heart problems or serious heart rhythm problems.
- have any other medical conditions such as weakening of the blood vessels in the brain, inflammation of the blood vessels, have had a stroke
- have eye problems, including increased pressure in your eye, glaucoma or trouble seeing close-up
- take any medicines for any other condition
- have painful or long-lasting erections
- have serious heart problems. You should be examined by a Heart Specialist before you take Ritalin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Ritalin LA should not be taken during pregnancy unless your doctor specifically advises you.

It may affect your developing baby, if you take it during pregnancy.

Do not breast feed while you are on Ritalin LA as the active ingredient in Ritalin LA can pass into the breast milk.

Children under 6 years

- Do not use Ritalin LA in children under 6 years of age.

Children under 18 years of age

- Your doctor needs to take a detailed history and evaluation before you take Ritalin LA.

Children may have slower growth if taking Ritalin LA for a long time.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take Ritalin LA if:

- you are taking monoamine oxidase inhibitors (MAOI) or have taken this medicine in the last 2 weeks.

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

- medicines that increase blood pressure;
- tricyclic antidepressants (treats depression);

- alpha 2 agonists (treat high blood pressure);
- oral anticoagulants (prevent blood clots);
- anticonvulsants (treat fits/seizures);
- medicines that treat mental illnesses (antipsychotics)
- phenylbutazone (treats pain or fever);
- medicines that influence dopamine levels e.g. disease which affects movement (Parkinson's disease);
that change the level of serotonin in the body such as sertraline or venlafaxine that are used to treat depression.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ritalin LA.

4. How do I take Ritalin LA?

How much to take

- **Your doctor will decide the appropriate dose for you.**
- The recommended starting dose of Ritalin LA in adults is 20 mg once daily.
- Daily doses above 80 mg are not recommended for adults.
- The recommended starting dose in children aged 6 years and older is 5 mg (refer to Ritalin 10 CMI).
- Daily doses above 60 mg are not recommended for children 6 years and above.

- **Your doctor may adjust your dose or ask you to discontinue the medication based on your response.**
- If you do not understand your dose, ask your doctor or pharmacist for help.
- Follow the instructions provided and use Ritalin LA until your doctor tells you to stop.

When to take Ritalin LA

- Ritalin LA should be taken orally once daily in the morning and as per your doctor's instructions.
- Ritalin LA capsule may be swallowed as whole with a glass of water.
- The capsules may be taken with or without food but always ensure to take them in the same way (e.g. always with food or always without food).
- **Consult your doctor if you do not understand how to take your medicine.**
- **Ritalin LA capsules and/or their contents should not be crushed, chewed or divided.**

If you have problems swallowing the capsules:

- The capsule contents can be sprinkled onto cold applesauce but should be swallowed **WITHOUT** chewing.
- **Do not store the drug and food mixture for future use.**

If you forget to take Ritalin LA

Ritalin LA should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- Take the medicine as prescribed by your doctor. Do not take it more often and do not use it for longer than your doctor advises you - this medicine can be addictive.

If you use too much Ritalin LA

If you think that you have used too much Ritalin LA, you may need urgent medical attention.

Symptoms of overdose:

- vomiting, headache, sweating, very high fever, high blood pressure, dryness of mucous membranes.
- agitation, euphoria (feeling of extreme happiness), severe confusion, seeing, feeling or hearing things that are not there (hallucinations)
- tremors
- unusually increased reflexes
- muscle twitching
- convulsions (may be followed by coma)
- flushing, fast heart rate, fast or irregular heartbeats

- dilated pupils and temporary paralysis or weakness of muscles.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Ritalin LA?

Things you should do

Take your medicine as directed by your doctor.

Make sure you keep any doctor's or specialist appointments as your doctor needs to assess your treatment periodically. Your doctor may check your or your child's blood pressure, height, weight, blood pressure and do some blood tests regularly.

Call your doctor straight away if you:

- Have any chest pain, fainting or other possible heart problems.
- Have any abnormal thoughts, over-active/excited or uninhibited actions, aggressive behaviour, are seeing things.

- Have fits or tics
- Have eye problems
- Have slurred speech, confusion, loss of coordination, sudden numbness
- Have painful or long-lasting erections.

Remind any doctor, dentist or pharmacist you visit that you are using Ritalin LA.

Things you should not do

- **Do not stop using this medicine suddenly without first consulting with your doctor.** You may need medical supervision if you have interrupted the treatment.
- **Do not change the dose without consulting your doctor.**
- **Do not take this drug to treat any other problems unless your doctor tells you to.**
- Do not give this medicine to anyone else, even if their condition seems like yours.

Keep all doctors and specialists appointments.

Misuse of Ritalin LA may cause sudden death and other serious heart problems.

Growth in children

- Some children taking Ritalin LA for a long time can have a slower than normal growth.

Medicines that raise serotonin

- For example sertraline, venlafaxine used to treat depression.
- If you feel restless, have tremor, abnormal high temperature, nausea, vomiting - stop using Ritalin LA.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ritalin LA affects you.

Ritalin LA may cause dizziness, drowsiness, blurred vision, or hallucinations (seeing or hearing things that aren't there) in some people.

If you have any of the above symptoms, do not drive, use machines, or engage in any other potentially hazardous activities.

Drinking alcohol

Do not drink alcohol while taking Ritalin LA.

Alcohol can make the side effects worse. Check to make sure food and other medicines taken do not contain alcohol.

Ritalin LA may give a false positive lab test when testing for drug use. This includes testing used in sport.

Looking after your medicine

- Store below 30°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Problems of the brain, spinal cord and nerves:</p> <ul style="list-style-type: none">• headache, dizziness• drowsiness or sleepiness• shaking of the body (tremor)• emotional problems - excitement, restlessness• rapid, extreme or unpredictable mood changes/mood swings• nervousness• being obsessed with one thing• feeling aggressive• feeling depressed• trouble falling asleep, sleeping problems• unusual active or depressed mood• confusion, disoriented <p>Heart problems:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • a problem with heart rate or heart rhythm • changes in blood pressure and heart rate (usually an increase) <p>Infections:</p> <ul style="list-style-type: none"> • sore throat • runny nose, nasal congestion • cough • sneezing • fever <p>Eating problems:</p> <ul style="list-style-type: none"> • decreased appetite • decreased weight • reduced weight gain <p>Mental illness:</p> <ul style="list-style-type: none"> • grind, gnash, or clench your teeth • irritability • feeling uneasy or worried - agitation • nervousness <p>Gut problems:</p> <ul style="list-style-type: none"> • nausea • dry mouth 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • stomach pain or upset • feeling full soon after eating • indigestion • vomiting • toothache • diarrhoea • constipation <p>Skin problems:</p> <ul style="list-style-type: none"> • rash • skin blisters • itchy skin • pink or red itchy rashes • hair loss • uncontrollable sweating <p>General problems:</p> <ul style="list-style-type: none"> • feeling jittery • bed wetting • tiredness • slow growth <p>Blood-related problems:</p> <ul style="list-style-type: none"> • fingers feel numb, have pins and needles or turn blue/purple • extreme hand or feet coldness 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • temporary muscle weakness, loss of skin sensation <p>Bones, joint problems:</p> <ul style="list-style-type: none"> • joint stiffness or pain • decreased ability to eat or speak • locked jaw, trouble opening the mouth, tooth/neck/face pain • muscle cramping • muscle pain or twitch <p>Eye problems:</p> <ul style="list-style-type: none"> • blurred eyesight • double vision • dilated pupils • trouble seeing <p>Lung problems:</p> <ul style="list-style-type: none"> • cough <p>Body system which fights disease:</p> <ul style="list-style-type: none"> • swelling of the ears <p>Reproductive problems:</p> <ul style="list-style-type: none"> • increased breast size in males 	

Serious side effects

Serious side effects	What to do
<p>Problems of the brain, spinal cord and nerves:</p> <ul style="list-style-type: none"> • twitching, jerking • fingers or toes feeling cold, numb, tingling and changing colour • fits • muscle twitching or tics • uncontrollable writhing of arms/legs, face or body <p>Heart problems:</p> <ul style="list-style-type: none"> • very fast heart rate • chest pain • irregular beating of the heart • severe headache or confusion, weakness, unable to move (paralysis), trouble speaking <p>Mental illness:</p> <ul style="list-style-type: none"> • thoughts of killing yourself 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • seeing, hearing or feeling things that aren't there • high temperature and muscle stiffness • drug abuse or dependence <p>Body system which fights disease:</p> <ul style="list-style-type: none"> • sore throat with fever/ chills • swelling of face, throat, lips, tongue; trouble breathing • tiredness with more infections or bleeding <p>Blood problems:</p> <ul style="list-style-type: none"> • bruising <p>Reproductive problems:</p> <ul style="list-style-type: none"> • prolonged erection, penis discomfort 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ritalin LA contains

Active ingredient (main ingredient)	Methylphenidate hydrochloride.
Other ingredients (inactive ingredients)	sugar spheres (sucrose and maize starch), methacrylic acid copolymer, purified talc, triethyl citrate, macrogol 6000, gelatin, titanium dioxide, iron oxide yellow (10, 30, 40 mg and 60 mg

	capsules only), iron oxide black (10, 40 mg and 60 mg capsules only), iron oxide red (40 mg and 60 mg capsules only) and TekPrint SW 8010.
Potential allergens	Sucrose, animal product

Do not take this medicine if you are allergic to any of these ingredients.

What Ritalin LA looks like

Ritalin LA are modified release capsules that present as follows:

10 mg containing white to off-white beads in a light brown opaque hard gelatin capsule with the imprint of NVR on the cap and R10 on a white opaque body in tan-coloured ink.

20 mg containing white to off-white beads in a white opaque hard gelatin capsule with imprint NVR on the cap and R20 on body in tan-coloured ink.

30 mg containing white to off-white beads in a yellow opaque hard gelatin capsule with the imprint NVR on cap and R30 on body in tan-coloured ink.

40 mg containing white to off-white beads in a light brown opaque hard gelatin capsule with the imprint NVR on cap and R40 on body in tan-coloured ink.

60 mg containing white to off-white beads in a light brown opaque cap and a yellow opaque body hard gelatin capsule with imprint NVR on cap and R60 on body in tan-coloured ink. Not all presentations are available.

Australian Registration Number

Ritalin LA 10 mg: AUST R 160228

Ritalin LA 20 mg: AUST R 82957

Ritalin LA 30 mg: AUST R 82958

Ritalin LA 40 mg: AUST R 82959

Ritalin LA 60 mg: AUST R 236251

Who distributes Ritalin LA

Ritalin LA capsules are supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1 800 671 203

Web site: www.novartis.com.au

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