

RITALIN[®] TABLET

Methylphenidate Hydrochloride (10mg)

RITALIN[®] LA CAPSULE

Methylphenidate Hydrochloride (20 mg, 30 mg)

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What Ritalin is used for

Ritalin is used for the treatment of attention-deficit/hyperactivity disorder (ADHD).

About 3% of children suffer from this disorder, which makes them unable to sit still and/or concentrate on tasks for any length of time. Children with this disorder may have difficulty in learning and doing schoolwork. They may frequently become difficult to manage both in school and at home. Adults with ADHD often find it hard to concentrate.

Ritalin is part of an ADHD treatment program which will usually also include psychological, educational and social therapy.

Ritalin is also used for the treatment of narcolepsy (Ritalin tablets only) in adults.

Narcolepsy is a sleep-attack disorder. People with narcolepsy experience recurring attacks of irresistible day-time sleepiness despite adequate night-time sleep. Ritalin LA capsules are not used to treat narcolepsy.

How Ritalin works

ADHD

Ritalin works by improving the activity of certain parts of the brain which are underactive. Ritalin improves attention and concentration, and reduces impulsive behaviour.

Narcolepsy

Ritalin relieves excessive day-time sleepiness in people suffering from narcolepsy.

Before you use Ritalin

Ritalin will only be prescribed by a doctor. Follow all the doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

- When you must not use it

- are allergic (hypersensitive) to methylphenidate or to any of the other ingredients of Ritalin listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.
- suffer from anxiety, tension or agitation.
- have any thyroid problems.
- have ever had heart problems - such as a heart attack, irregular heartbeat, chest pain, heart failure, heart disease or were born with a heart problem.
- have very high blood pressure or narrowing of the blood vessels (that can cause pain in the arms and legs).
- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 2 weeks. (please see section "Taking other medicines").
- have increased eye pressure.
- have a tumor of the adrenal gland called pheochromocytoma.
- have uncontrolled speech and body movements (Tourette's syndrome) or if any other family members suffer from Tourette's syndrome.

If you think that any of these may apply to you, tell the doctor without taking Ritalin.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or think you may be pregnant, tell your doctor. Ritalin is not

to be used during pregnancy unless specifically prescribed by your doctor.

Breast-feeding

If you are breast-feeding, tell your doctor. Do not breast-feed during your treatment with Ritalin. The active substance in Ritalin can pass into human milk.

- Before you start to use it

Take special care with Ritalin if you:

- have a history of drug or alcohol abuse.
- have had fits.
- have high blood pressure.
- have any heart defects.
- have or have had any disorder of the blood vessels in the brain, e.g. weakening of blood vessel wall (aneurysm), stroke, inflammation of blood vessels.
- have an acute mental disorder that causes abnormal thinking and perceptions (psychosis) or makes you feel unusually excited, over-active and un-inhibited (acute mania) – your doctor will have told you if you have this.
- have psychotic symptoms such as seeing or feeling things that are not really there (hallucinations).
- have aggressive behaviour.
- have any suicidal thoughts or behaviour.
- have motor tics or if any other family members suffer from tics. Signs of tics are hard to control, repeated twitching of any parts of the body or repeating sounds and words.
- have or develop eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness).

If any of these applies to you, tell your doctor. The doctor will decide if you can start taking or continue to take Ritalin.

Some children taking Ritalin for a long time may have slower growth than normal.

Chronic abuse of Ritalin can lead to marked tolerance and psychological dependence.

Taking Ritalin with food and drink

Do not drink alcohol while taking Ritalin. Alcohol may make the side effects of Ritalin worse.

Remember that some foods and medicines contain alcohol.

While taking Ritalin, be cautious with consuming stimulants including caffeine containing medications, foods, or beverages (e.g., energy drinks). As these are also stimulants, using them together with Ritalin can increase side effects such as fast or irregular heartbeat and high blood pressure.

Children and adolescents

Ritalin is not recommended for children under 6 years of age.

Drug testing

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

- Taking other medicines

Do not take Ritalin if you are taking:

- a medicine called a 'monoamine oxidase inhibitor' (MAOI, used to treat depression) or have taken an MAOI in the last 2 weeks. Taking an MAOI with Ritalin may cause a sudden increase in your blood pressure (please see section "When you must not use it").

It is important that you tell your doctor or pharmacist if you are taking any of the following medicines, as it may be necessary to change the dose or in some cases to stop one of the medicines:

- medicines that increase blood pressure.
- tricyclic antidepressants (used to treat depression).
- alpha 2 agonists like clonidine (used to treat high blood pressure)
- oral anticoagulants (used to prevent blood clots).
- some anticonvulsants such as phenobarbital, phenytoin and primidone (used to treat seizures).
- phenylbutazone (used to treat pain or fever).

- medicines that influence level of dopamine in the body (dopaminergic medicines, dopamine antagonists i.e. haloperidol, used to treat Parkinson's disease or psychosis).
- medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression).

Take special care with Ritalin if you:

- experience a combination of the following symptoms: restlessness, tremor, sudden muscle contractions, abnormal high temperature and nausea and vomiting while taking methylphenidate with medicines that raise the level of serotonin in the body. Stop treatment with methylphenidate and medicines that raise the level of serotonin in the body and tell your doctor immediately.

If any of these applies to you, tell your doctor. The doctor will decide if you can continue to take Ritalin.

How to use Ritalin

The doctor will decide on the most suitable dosage according to your medical need and response. Follow the doctor's instructions carefully. Do not exceed the recommended dose. Only the Ritalin LA formulation is used to treat adult ADHD individual.

- How much to use

Do not change the dose without talking to the doctor.

If you have the impression that the effect of Ritalin is too strong or too weak, talk to your doctor.

Children (6 years and above)

The doctor will tell you how many Ritalin tablets or capsules to give your child. The doctor will usually start treatment with a low dose and increase it gradually as required. The highest recommended daily dose is 60 mg.

Adults

Your doctor will tell you exactly how many tablets or capsules to take. The usual daily dose is 20 to 30 mg but some individual may need more or less than this.

The highest recommended daily dose is 60 mg for the treatment of narcolepsy and 80 mg for the treatment of ADHD.

- When to use Ritalin

- You can take Ritalin tablets and Ritalin LA capsules with or without food.
- **Ritalin tablet 10 mg:** Take Ritalin once or twice daily (e.g. at breakfast or/and lunch time). Swallow the tablet with water.
- **Ritalin LA capsule:** Take Ritalin LA once daily in the morning. Swallow the capsule whole with water. Do not crush, chew or divide the capsule or the contents. If you are unable to swallow the Ritalin LA capsule, 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 medicine/food mixture.
 - Do not store any medicine/food mixture for future use.

One Ritalin LA capsule provides an initial release of the active substance and a second release approximately 4 hours later. This is why Ritalin LA can be taken in the morning at home without the need for another dose at midday.

Ritalin LA capsules taken once daily are comparable to Ritalin tablets taken twice a day. The doctor will advise you how to take Ritalin LA capsules, especially if you were previously taking Ritalin tablets.

In some people, Ritalin may cause sleeplessness. To avoid difficulty in falling asleep, the last dose of Ritalin should be taken before 6 p.m. unless the doctor recommends otherwise.

- How long to use Ritalin

Use this medicine exactly as instructed by the doctor.

Do not use more of it, do not use it more often, and do not use it for longer than instructed by the doctor. If used inappropriately, this medicine may become addictive.

Treatment for ADHD varies in length from individual to individual. It may be stopped during or after puberty.

The doctor may discontinue Ritalin periodically to see whether it is still needed.

- If you forget to use Ritalin

If a dose of Ritalin is missed, you should take it as soon as possible. Then make sure to wait the same amount of time as usual before you take the next dose. Do not take a double dose of Ritalin to make up the missed dose. If you have any questions about this, check with the doctor.

- If you use too much (overdose)

If too many Ritalin tablets or capsules have been accidentally taken, go immediately to the doctor or to the nearest hospital emergency department. Tell the doctor at what time the tablets or capsules were taken. You may require medical attention.

The symptoms of overdose are vomiting, agitation, headache, tremors, muscle twitching, irregular heart beat, flushing, fever, sweating, dilated pupils, confusion, and fits; muscle spasms, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

While you are using Ritalin

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Ritalin.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop Ritalin without talking to the doctor. It may be necessary to reduce the daily dose gradually before stopping completely. You will need medical supervision after having interrupted the treatment.

- Things to be careful of

Driving and using machines

Ritalin may cause dizziness, drowsiness, blurred vision, hallucination or other central nervous system side effects, which can affect concentration. If you experience such symptoms, do not drive or use machines, or do other activities that need quick reactions.

Having an operation

If you are going to have an operation, tell the doctor that you are on treatment with

Ritalin. You should not take Ritalin on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

- Monitoring during treatment with Ritalin

To see if Ritalin is having any unwanted effects, the doctor will check your general health indicators (e.g. blood pressure, heart rate) from time to time and will also monitor the growth of children taking Ritalin. Blood tests will be carried out to monitor the amount of blood cells (white blood cells, red blood cells and platelets) if a person takes Ritalin for a long time.

Side effects

Take special care with Ritalin if you:

- experience abnormally sustained or frequent and painful erections of the penis on Ritalin treatment or after treatment discontinuation. This can occur in any age group and may need urgent medical treatment. If this occurs, tell your doctor immediately.

As with all medicines, Ritalin can have some side effects, although not everybody gets them. These are usually mild to moderate and generally transient.

Some side effects could be serious:

if you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Common: may affect up to 1 in every 10 people

- uncontrollable twitching and jerking (sign of dyskinesia).
- fast heartbeat
- fingers and toes feeling numb, tingling and changing color when cold

Rare: may affect up to 1 in every 1,000 people

- chest pain

Very rare: may affect up to 1 in every 10,000 people

- a sore throat and fever or chills (signs of a low white blood cell count).
- swelling of lips or tongue, or difficulty in breathing (signs of severe allergic reaction).
- seeing or feeling things that are not really there (hallucinations).

- fits.
- uncontrollable writhing movements of the limb, face and/or trunk.
- muscle twitching.
- bruising.
- skin blisters or itching (sign of exfoliative dermatitis).
- red blotches on the skin (sign of erythema multiforme).
- sudden high fever, very high blood pressure and severe convulsions (Neuroleptic Malignant Syndrome).

Not known: frequency cannot be estimated from the available data

- abnormal decrease in the levels of all type of blood cells. This is associated with anaemia, decreased platelets, and decreased white blood cells. This can lead to fatigue, increased risk of bleeding, and/or increased risk of infection. This may be serious or life threatening (pancytopenia).
- thoughts or attempts of killing yourself (suicidal ideation or attempt (including completed suicide)).
- prolonged erection, causing discomfort of the penis (sign of priapism)

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common: may affect more than 1 in 10 people

- sore throat and runny nose
- decreased appetite
- nervousness
- difficulty in falling asleep
- nausea, dry mouth

Common: may affect up to 1 in every 10 people

- anxiety, restlessness, sleep disorder, agitation
- headache, dizziness, sleepiness
- involuntary shaking of the body
- changes in blood pressure, abnormal heart rhythm, strong pounding of heartbeat
- cough
- vomiting, stomach pain, indigestion, toothache
- skin rash, itchy rash and hives, fever, hair loss
- excessive sweating
- joint pain
- decreased weight

- feeling jittery
- feeling depressed (depression)
- feeling aggressive (aggression)
- excessive teeth grinding (bruxism)

Uncommon: may affect up to 1 in every 100 people

- Spasm of the jaw muscles that makes it difficult to open the mouth (trismus)

Not known: frequency cannot be estimated from the available data

- Stuttering (dysphemia), feeling irritated, mood changes, abnormal behavior or thinking, anger, over-active and un-inhibited (mania), feeling disorientated, low in sex drive, lack of interest, doing things over and over again, over-focusing, confusion, dependence
- temporary muscle weakness, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain, migraine
- double vision, dilated pupils, trouble seeing
- swelling of the ears (auricular swelling, a symptom of allergic reaction)
- stopped heartbeat, heart attack
- throat pain, shortness of breath
- diarrhea, constipation
- redness of the skin (erythema), skin rash (fixed eruption)
- muscle pain, muscle twitching
- bedwetting in children during the night (enuresis)
- inability to develop or maintain an erection, swelling of the breasts in men
- tiredness
- increased eye pressure (increased intraocular pressure)

Additional side effects that have occurred with other medicines containing the same drug substance as Ritalin:-

Not known: frequency cannot be estimated from the available data

- blood in the urine
- sudden death of heart origin
- abnormal sounds heard between heart beat

If any of the above side effects occur, tell your doctor. If you notice any other side effects not mentioned in this leaflet, please inform your doctor or your pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Ritalin

- Storage

- Do not use after the expiry date shown on the box.
- Do not use if the pack is damaged or shows signs of tampering.
- **Ritalin tablet 10 mg:** Do not store above 30°C. Store in the original package in order to protect from moisture.
- **Ritalin LA capsule:** Do not store above 30°C. Keep the bottle tightly closed.
- Keep out of the reach and sight of children.

- Disposal

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.

Product Description

- What it looks like

Ritalin tablet 10mg: Immediate-release tablet, divisible, white, round, flat, with bevelled edges. One side bears the imprint “CG”, the other “A/B” and score. May contain dark specks.

Ritalin LA capsule 20 mg: Modified-release capsule, hard, white opaque gelatin capsule, imprinted with “NVR” in tan ink on the cap and “R20” in tan ink on the body, containing white to off-white beads that are roughly spherical in shape.

Ritalin LA capsule 30 mg: Modified-release capsule, hard, yellow opaque gelatin capsule, imprinted with “NVR” in tan ink on the cap and “R30” in tan ink on the body, containing white to off-white beads that are roughly spherical in shape.

- Ingredients:

Ritalin tablet 10 mg

- Active ingredients
 - The active substance of Ritalin tablet is methylphenidate hydrochloride. Each tablet

contains 10 mg methylphenidate hydrochloride. Ritalin tablets are divisible.

- Inactive ingredients
 - The other ingredients are calcium phosphate tribasic, lactose monohydrate, wheat starch, gelatine, magnesium stearate, and talc.

Ritalin LA capsule 20 mg or 30 mg

- Active ingredients
 - The active substance of Ritalin LA capsules is methylphenidate hydrochloride. Each capsule contains 20 mg or 30 mg methylphenidate hydrochloride.
- Inactive ingredients
 - The other ingredients are ammonio methacrylate copolymer type B, gelatine, methacrylic acid copolymer type A, macrogol 6000, sugar spheres, talc, titanium dioxide (E171), triethyl citrate, and yellow iron oxide (E172) (30 mg capsules only).

- MAL Number

Ritalin Tablet 10mg:

MAL19910002ACRZ

Ritalin LA Modified-Release Capsule 20mg: MAL05092201ACRZ

Ritalin LA Modified-Release Capsule 30mg: MAL05092208ACRZ

Manufacturer

Ritalin Tablet 10mg:

Siegfried Barbera S.L.,
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Ritalin LA Modified-Release Capsule

20mg, 30mg:

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