

Ritalin[®] tablet

methylphenidate hydrochloride

10 mg immediate release tablets

SR 20 mg slow release tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ritalin tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.medsafe.govt.nz.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Ritalin is used for

Ritalin tablets contain the active ingredient methylphenidate hydrochloride. Methylphenidate hydrochloride is a central nervous system stimulant. Like all medicines containing central nervous system stimulants, Ritalin will be given to you only under close medical supervision and after diagnosis.

Ritalin tablets have two uses. They are used to treat:

- Attention Deficit Hyperactivity Disorder (ADHD); and
- Narcolepsy

Your doctor may have prescribed it for another purpose.

This medicine should not be used to prevent or treat normal fatigue.

ADHD

ADHD or hyperkinetic disorder is a behavioural disorder in children, adolescents, and adults. About 3% of children suffer from ADHD, which makes them unable to sit still or concentrate on tasks for any length of time. They may have trouble learning and doing school work. They frequently become difficult to manage, both in school and at home.

Ritalin is thought to work by regulating specific chemicals in the brain that affect behaviour. It helps to focus attention, shut out distraction and allows impulsive people to think before they act. If successful, it will

enhance an inattentive person's natural ability.

Ritalin is part of a treatment program which usually includes physiological, educational, and social therapy.

Narcolepsy

Narcolepsy is a sleep-attack disorder. It is not a normal fatigue state. People with narcolepsy have recurring attacks of irresistible day-time sleepiness in spite of having enough sleep at night. It can be diagnosed by a doctor by recording wake-sleep patterns.

Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.

This medicine is only available with a doctor's prescription and your doctor has special permission to prescribe it.

There is not enough information to recommend its use in children under 6 years old.

Note: Ritalin is a controlled drug B2.

It should be kept in a secure place and under no circumstances should it be given to anyone else.

Before you/your child take Ritalin

When you must not take it

Do not take Ritalin if you or your child are allergic (hypersensitive)

to methylphenidate (the active ingredient in Ritalin) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Ritalin if you or your child have any of the following medical conditions:

- periods of severe anxiety, tension or agitation
- Tourette's syndrome (a condition with uncontrolled speech and body movements or tics) or you have a family history of this disorder
- glaucoma (increased pressure in the eye)
- an overactive thyroid or other thyroid problems
- heart problems such as heart attack, irregular heartbeat, chest pain (angina), heart failure, heart disease or if you were born with a heart problem
- very high blood pressure (hypertension) or narrowing of the blood vessels (arterial occlusive disease, that can cause pain in the arms and legs)
- severe depression or other mental illness
- pheochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney)

If you are not sure whether any of the above medical conditions apply to you or your child, check with your doctor.

Do not take Ritalin if you or your child are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the past 14 days.

Taking Ritalin together with MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high

blood pressure and severe convulsions.

Ask your doctor or pharmacist if you are not sure if you or your child have been taking one of these medicines.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you/your child start to take it

Tell your doctor if you or your child are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you or your child are prone to allergies.

Tell your doctor if you or your child have intolerance to lactose or gluten.

This medicine contains lactose and wheat starch.

Tell your doctor if you or your child have any of the following medical conditions or behaviours:

- any heart defects (e.g. structural cardiac abnormality)
- a family history of sudden death or irregular heart beat
- hardening of the arteries
- any other current or previous heart problems
- any disorders of the blood vessels in the brain, e.g. weakening of the blood vessel (aneurysm), stroke, or inflammation of blood vessels (vasculitis)
- severe depression, bipolar disorder or other mental illness
- epilepsy (seizures, convulsions, or fits)
- high blood pressure
- history of alcohol or drug abuse or dependence
- tics (muscle twitching which is usually in the face or shoulders)

or if your brothers or sisters have tics

- acute mental disorders that cause abnormal thinking and perceptions (psychosis) or feeling unusually excited, over-active and un-inhibited (acute mania) – your doctor will have told you if you have this
- psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- aggressive behaviour
- suicidal thoughts or behaviour.

Your doctor may want to take special precautions if you or your child have any of the above conditions.

Tell your doctor if you are pregnant or breast-feeding. Ask your doctor about the risks and benefits of taking Ritalin in this case. Ritalin is not to be used during pregnancy unless specifically prescribed by your doctor.

This medicine may affect your developing baby if you take it while you are pregnant.

Do not breast-feed during treatment with Ritalin.

The active ingredient in Ritalin can pass into the breast milk.

Taking other medicines

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

Some medicines and Ritalin may interfere with each other. These include:

- medicines that increase blood pressure
- alpha 2 agonists like clonidine (used to treat high blood pressure)
- oral anticoagulants or warfarin (medicines used to prevent blood clots)

- some anticonvulsants (medicines used to treat epilepsy or fits)
- medicines used to treat depression, such as tricyclic antidepressants and monoamine oxidase inhibitors (MAO inhibitors)
- phenylbutazone (used to treat pain or fever)
- guanethidine
- anaesthetics
- medicines that influence the level of dopamine in the body (dopaminergic medicines 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 like sertraline and venlafaxine).

You or your child may need to take different amounts of your medicines or you or your child may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you or your child start taking this medicine.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Ritalin.

How to take Ritalin

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide on the most suitable dosage according to the

individual patient's medical need and response.

For children and adolescents, the maximum daily dose of Ritalin tablet(s) is 60 mg.

For adults, the maximum daily dose of Ritalin tablet(s) is 60 mg for narcolepsy and 80 mg for ADHD.

Do not exceed the recommended dose.

Children aged 6 or over

Ritalin tablet 10 mg

The usual starting dose is 5 mg (half a tablet) once or twice each day. If necessary, the dose can be increased by 5 or 10 mg each week up to a maximum of 60 mg (6 tablets) each day.

If the dose is one-half tablet, there is a break-line on the tablet to help you cut it. You can buy a tablet cutter from your pharmacist to make sure the dose is accurate.

Ritalin SR tablet 20 mg

Your doctor will decide on the most suitable dosage. The usual dose is 20 mg once daily.

Adults

Ritalin tablet 10 mg

The usual dose is 20 to 30 mg (2-3 tablets) each day but some people may need more or less than that.

Ritalin SR tablet 20 mg

Your doctor will decide on the most suitable dosage. How to take it

Take Ritalin SR immediately after meals and preferably after a substantial breakfast. Do not crush or chew Ritalin SR tablets.

You can take Ritalin tablets with or without food (e.g. at breakfast and/or lunch).

Swallow the tablet(s) with a full glass of water or other liquid.

If the tablet(s) upset you or your child's stomach, you or your child

can take them with food, but always take them in the same way (e.g. always with food or always without food).

That way the effect will always be the same.

When to take it

If you find that you or your child have trouble sleeping, talk to your doctor about the best time to take the last dose of Ritalin for the day.

Each dose is usually taken 1 or 2 hours before the greatest effect is needed. For example, a child may take a dose at 7:00 a.m. so that improved concentration begins when school starts. If the child tends to misbehave during the lunchtime play period, the next dose can be taken before the lunch break.

It may be necessary to take a combination of the slow release 20 mg tablets with the immediate release 10 mg tablets to achieve the best results.

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

The effects of slow release 20 mg tablets are maximised when taken with a meal. Check carefully with your doctor when and how to take this combination.

How long to take Ritalin

Continue taking Ritalin tablet / Ritalin SR tablet for as long as your doctor tells you.

This medicine helps to control your or your child's symptoms but does not cure your condition. Your doctor will check your or your child's progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

If you are unsure, talk to your doctor.

Treatment for ADHD varies in length from patient to patient. During treatment for ADHD, your doctor may stop Ritalin every so often (e.g. over weekends or school holidays and long vacations) to see whether it is still needed. Breaks from treatment also help to prevent a slow-down in growth that sometimes happens when children take this medicine for a long time.

If you/your child forget to take it

If you or your child forget to take a dose of Ritalin, take the dose as soon as you remember. Then make sure to wait the same amount of time as usual before you or your child take the next dose. For example, if there are usually 4 hours between doses, wait 4 hours before taking the next dose and so on for the rest of that day. On the next day go back to your usual times.

Do not take a double dose to make up for the one that you or your child missed.

Your chance of an unwanted side effect may be increased if you do.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you/your child take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre, Dunedin (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Ritalin. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include vomiting, agitation, headache, tremors, muscle twitching, irregular heartbeat,

flushing, fever, sweating, dilated pupils, breathing problems, confusion seizures and muscle spasms accompanied by fever and red-brown urine.

While you are taking Ritalin

Things you must do

Take Ritalin exactly as your doctor has prescribed.

Like all stimulants, this medicine may become habit-forming and can be abused by some people. If you or your child take it correctly as instructed by your doctor, abuse or dependence should not be a problem, either now or later in life.

Be sure to keep all of your doctor's appointments so that your or your child's progress can be checked.

Your doctor will want to check blood pressure, height, weight and do blood tests from time to time to prevent unwanted side effects from happening.

If your child is not growing or gaining height or weight as expected treatment with Ritalin may need to be interrupted.

If you become pregnant while taking Ritalin, tell your doctor.

Your doctor can discuss with you the risks and benefits of taking it while you are pregnant.

If you/your child are about to be started on any new medicine, remind your doctor and pharmacist that you/your child are taking Ritalin.

Tell any doctor, dentist or pharmacist who treats you/your child that you are taking Ritalin.

Things you must not do

Do not drink alcohol whilst you are taking Ritalin. Remember that some foods and medicines contain alcohol.

Alcohol can worsen some of the unwanted effects of this medicine, such as dizziness and drowsiness.

Do not stop treatment without first checking with your doctor.

If you/your child suddenly stop taking this medicine, your condition may reappear or you may get unwanted effects such as depression. To prevent this, your doctor may want to gradually reduce the amount of medicine you take each day before stopping it completely.

You will need medical supervision after having interrupted the treatment.

Do not change the dose without talking to your doctor. If you have the impression that the effect of Ritalin is too strong or too weak, talk to your doctor.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give it to anyone else, even if their condition seems similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you/your child to be alert while you are taking Ritalin until you know how it affects you.

This medicine may cause hallucinations, dizziness, drowsiness, blurred vision, or other central nervous system side effects which can affect concentration in some people. If you experience any of these symptoms, do not drive, use machines, or do anything else that needs quick reactions or could be dangerous.

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

Some children taking Ritalin for a long time may have slower than normal growth, but they usually catch up once the treatment is stopped.

In some patients Ritalin may cause stomach upset, loss of appetite and difficulty sleeping, especially at the start of treatment. Your doctor can usually help to reduce these symptoms by lowering the dose of Ritalin or changing the times when the tablets are taken.

If you experience abnormally sustained or frequent and painful erections of the penis on Ritalin 10 treatment or after treatment discontinuation, you may need urgent medical treatment. This can occur in any age group.

If this occurs, tell your doctor immediately.

If taking Ritalin with medicines that raise the level of serotonin in the body (serotonergic medicines, e.g. sertraline and venlafaxine used to treat depression) and you experience a combination of the following symptoms: restlessness, tremor, sudden muscle contractions, abnormal high temperature, nausea and vomiting stop treatment with Ritalin and these medicines and tell your doctor immediately.

Tell your doctor if you are going to have an operation.

You should not take Ritalin LA on the day of your operation 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ritalin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your

doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea (feeling sick), vomiting or stomach pain
- upset stomach, or indigestion
- loss of appetite
- sore throat and runny nose
- loss of weight and slower growth in children
- feeling nervous, anxious or agitated
- feeling jittery
- restlessness or inability to sleep
- dry mouth
- headache
- cough
- drowsiness
- dizziness
- irritability
- blurred vision or problems focussing your eyes
- muscle cramps
- hair loss
- hives
- joint pain
- toothache
- excessive sweating
- abnormal heart rhythm
- palpitations
- excessive emotional distress, or emotional excitement
- decreased weight
- feeling jittery
- feeling depressed
- feeling aggressive
- excessive teeth grinding
- spasms of the jaw muscles that makes it difficult to open the mouth
- stuttering
- bedwetting in children at night

Tell your doctor immediately or go to Accident and Emergency at

your nearest hospital if you notice any of the following:

- signs of allergy such as swelling of the face, lips or tongue, shortness of breath, wheezing or troubled breathing as these are signs of a severe allergic reaction
- weakness or paralysis of limbs or face, difficulty speaking, or unexplained fainting
- skin rash, itching, red blotches, blisters or peeling of the skin
- sudden increase in body temperature, sweating, fast heartbeat, chest pain, muscle stiffness and fluctuating blood pressure, which may lead to coma
- constant "flu-like" symptoms such as chills, fever, sore throat and runny nose, swollen glands, aching muscles or joints
- unusual bleeding or bruising
- unusual tiredness, shortness of breath when exercising, dizziness, pale skin
- involuntary shaking of the body (signs of tremor) such as uncontrollable twitching, jerking or writhing movements
- seizures (fits) or unexplained fainting
- pain or tightness in the chest
- fast or irregular heartbeat
- yellow colour to the skin or eyes, dark coloured urine or light coloured bowel motions
- confusion, delusions or hallucinations (seeing or feeling things that are not really there)
- excitement, overactivity and uninhibited behaviour
- severe or persistent headache
- uncontrolled speech and body movements (Tourette's syndrome)
- prolonged erection, causing discomfort of the penis (sign of priapism).
- Thoughts or attempts of killing yourself (suicidal ideation or

attempt, including completed suicide)

- Fingers and toes feeling numb, feeling cold, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon, peripheral coldness)

The above side effects may be serious. You may need urgent medical attention.

Additional side effects that occurred with other medicines containing the same drug substance of Ritalin:

- Inflammation of the nasal passages and throat
- Swelling of the ears (a symptom of allergic reaction);
- Feeling irritated, aggression, mood changes, abnormal behaviour or thinking, anger, excessive awareness of surroundings, feeling unusually excited, over-active and uninhibited (mania), feeling disorientated, changes in sex drive, lack of feeling or emotion, doing things over and over again, being obsessed with one thing, confusion, addiction
- Temporary muscle weakness, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischemic neurological deficit), migraine
- Double vision, dilated pupils, trouble seeing
- Stopped heartbeat, heart attack
- Sore throat, shortness of breath;
- Diarrhoea, constipation;
- Swelling of face and throat, redness of the skin, large red blotches on the skin appearing within a few hours of taking the medicine;
- Muscle pain, muscle twitching;
- Blood in the urine
- Swelling of the breasts in men

- Chest pain, tiredness, sudden death

- Abnormal sounds from heart.

Tell your doctor if any of these side effects occur or if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking Ritalin

Storage

- Keep the tablets in the original container until it is time to take a dose.
- Store Ritalin in a cool dry place, below 30°C.
- Do not store Ritalin or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines. Ritalin will keep well if it is cool and dry.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Ritalin 10 mg

Round white tablet, marked "CG" on one side and "AB" with a break-line on the other; packs of 30 tablets.

Ritalin SR 20mg

Round white to off white tablet marked "CIBA" on one side and "16:" on the other, packs of 100 tablets

Ingredients

Ritalin 10 mg tablets contain 10 mg of methylphenidate hydrochloride as the active ingredient. They also contain:

- lactose
- calcium phosphate (E341)
- gelatin
- magnesium stearate (E572)
- purified talc (E553b)
- wheat starch

Ritalin SR tablets contain 20mg of methylphenidate hydrochloride as the active ingredient. They also contain:

- lactose
- cetostearyl alcohol
- magnesium stearate (E572)
- hydroxypropyl methylcellulose (E464)
- polyoxyl 40 hydrogenated castor oil
- titanium dioxide
- talc (E553b)
- carnauba wax

Sponsor

Ritalin tablets are supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

Telephone 0800 354 335

® = Registered Trademark

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