

Ritalin[®] 10

methylphenidate hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ritalin 10 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.novartis.com.au.

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 10 is used for

Ritalin 10 tablets have two uses.

- They are used to treat Attention Deficit Hyperactivity Disorder (ADHD).

About 3% of children suffer from ADHD. It 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 10 is a central nervous system stimulant. It 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.

This medicine is part of a treatment program that usually includes psychological, educational and social therapy.

- Ritalin 10 tablets are also used to treat narcolepsy, a sleep-attack disorder.

People with narcolepsy have recurring attacks of irresistible day-time sleepiness in spite of having enough sleep at night. Narcolepsy can be diagnosed by a doctor by recording wake-sleep patterns.

Narcolepsy is not a normal fatigue state. This medicine should not be used to prevent or treat normal fatigue.

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

Your doctor may have prescribed it for another purpose.

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.

Ritalin 10 can be abused or lead to dependence. Keep Ritalin 10 in a safe place to prevent misuse and abuse.

Before you take Ritalin 10

When you must not take it

Do not take Ritalin 10 if you or your child are allergic to methylphenidate (the active ingredient) 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 10 if you or your child have any of the following medical conditions:

- periods of severe anxiety, tension or agitation
- Tourettes's syndrome or you have a family history of this disorder
- glaucoma (increased pressure in the eye)
- an overactive thyroid
- heart problems such as heart attack, irregular heartbeat, chest pain (angina), high blood pressure
- severe depression or other mental illness

- phaeochromocytoma (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 10 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 10 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 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 an 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:

- 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
- severe depression, bipolar disorder or other mental illness
- epilepsy (seizures or fits)
- high blood pressure
- alcoholism
- drug dependence
- tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics

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 going to have surgery.

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

Tell your doctor if you are pregnant or breast-feeding. Ask your doctor about the risks and benefits of taking Ritalin 10 in this case.

This medicine may affect your developing baby if you take it while you are pregnant. It is not known if the active ingredient in Ritalin 10 passes into the breast milk. Breast-feeding is not recommended while taking this medicine.

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 10 may interfere with each other. These include:

- medicines that increase blood pressure
- alpha 2 agonists like clonidine (used to treat high blood pressure)

- warfarin, a medicine used to prevent blood clots
- medicines for epilepsy (fits)
- medicines for depression, such as tricyclic antidepressants and MAO inhibitors
- clonidine

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.

How to take Ritalin 10

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

Ritalin 10 is available in tablets containing 10 mg of methylphenidate hydrochloride as the active ingredient.

For children aged 6 or over, 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.

For adults, the usual dose is 20 to 30 mg (2-3 tablets) each day but some people may need more or less than that. The maximum dose is 60 mg (6 tablets) each day.

How to take it

Take the tablets with a full glass of water. If they 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.

Take the tablets in 2 or 3 doses over the day unless your doctor tells you otherwise. 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 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.

How long to take it

Continue taking Ritalin 10 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.

During treatment for ADHD, your doctor may stop Ritalin 10 every so often (e.g. over weekends or school holidays) 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 forget to take it

If you or your child forget to take a dose of Ritalin 10, 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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Ritalin 10. 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 heart beat, flushing, fever, sweating, dilated pupils, breathing problems, confusion and seizures.

While you are taking Ritalin 10

Things you must do

Take Ritalin 10 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 your or your child's 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 10 may need to be interrupted.

If you become pregnant while taking Ritalin 10, tell your doctor.

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

If you or your child are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ritalin 10.

Tell any doctor, dentist or pharmacist who treats you or your child that you are taking Ritalin 10.

Things you must not do

Do not stop your treatment without first checking with your doctor.

If you 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.

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 to be alert while you are taking Ritalin 10 until you know how it affects you.

This medicine may cause hallucinations, dizziness, drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive, use machines or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking Ritalin 10.

Drinking alcohol is not recommended because it can worsen some of the unwanted effects of this medicine, such as dizziness and drowsiness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ritalin 10.

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
- loss of appetite
- loss of weight and slower growth in children
- feeling nervous or unable to sleep
- dry mouth
- headache
- drowsiness
- dizziness
- mood changes such as depression or irritability
- blurred vision or problems focussing your eyes
- muscle cramps
- hair loss

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

- weakness or paralysis of limbs or face, difficulty speaking, or unexplained fainting
- rash, itching, red blotches, blisters or peeling of the skin
- sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma
- constant "flu-like" symptoms such as chills, fever, sore throat, swollen glands, aching muscles or joints
- unusual bleeding or bruising
- unusual tiredness, shortness of breath when exercising, dizziness, pale skin
- uncontrollable twitching, jerking or writhing movements
- seizures (fits) or unexplained fainting
- pain or tightness in the chest
- fast or irregular heartbeat
- changes in blood pressure
- 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
- new or worsening aggressive behaviour
- severe or persistent headache

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; decrease in number of blood cells (red cells, white cells and platelets); swelling of the ears (a symptom of allergic reaction); feeling anxious, irritated and agitated, aggression, mood changes, abnormal behaviour or thinking,

anger, thoughts or attempts of suicide (including completed suicide), excessive awareness of surroundings, feeling unusually excited, over-active and un-inhibited (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; trembling, 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 ischaemic neurological deficit), migraine; double vision, dilated pupils, trouble seeing; stopped heart beat, heart attack; fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon'); cough, sore throat, shortness of breath; diarrhoea, constipation; swelling of face and throat, excessive sweating, 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; weight decreased, abnormal sounds from heart.

Tell your doctor 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 10

Storage

- Keep your medicine in the original container until it is time to take a dose.
- Store it in a cool dry place.
- Do not store Ritalin 10 or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

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.

Australian Registration Number:

Ritalin 10 tablet: AUST R 11052

Product description

What it looks like

Ritalin 10 tablets are round white tablets, marked CG on one side and AB with a break-line on the other; packs of 100 tablets.

Ingredients

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

- lactose
- calcium phosphate
- gelatin
- magnesium stearate
- purified talc
- wheat starch

Sponsor

Ritalin 10 tablets are supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited

ABN 18 004 244 160

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North Ryde NSW 2113

Telephone: 1 800 671 203

Web site: www.novartis.com.au

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This leaflet was prepared in August 2010.