

Rubifen

Methylphenidate hydrochloride

Immediate release tablets

Slow-release tablets

What is in this leaflet

This leaflet answers some common questions about Rubifen.

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

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

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

Keep this leaflet with the medicine. You may need to read it again.

What Rubifen is used for

Rubifen is used to treat a behavioural disorder called 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 schoolwork. They frequently become difficult to manage, both in school and at home.

Rubifen 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.

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

Rubifen is also used to treat narcolepsy, a sleep-attack disorder.

People with narcolepsy have recurring attacks of irresistible daytime sleepiness in spite of having enough sleep at night. A doctor can diagnose narcolepsy by recording wake-sleep patterns.

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

Ask your doctor if you have any questions about why Rubifen has been prescribed for you or your child. Your doctor may have prescribed it for another reason.

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 and elderly over 65 years because it has not been studied in these age groups.

Note: Rubifen 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 starts to use it

Do not take Rubifen if you/ your child have an allergy to methylphenidate (the active ingredient in Rubifen) or to any of the other ingredients listed at the end of this leaflet

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

Do not take Rubifen if you/ your child have any of the following medical conditions:

- periods of severe anxiety, tension, or agitation.
- severe depression, anorexia nervosa, suicidal tendency, bipolar disorder, or other mental illness
- tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics.
- Tourette's syndrome 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)

- pheochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney)
- currently taking or have taken a monoamine oxidase (MAO) inhibitor, medicines used to treat major depression (e.g. phenelzine, tranylcypromine) or medicines used in Parkinson's disease (e.g. selegiline) within the last 14 days

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 Rubifen 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/ your child are allergic to any other medicines, foods, dyes or preservatives. Your doctor will want to know if you/your child are prone to allergies.

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

- severe depression or other mental illness
- epilepsy (seizures or fits)
- high blood pressure
- alcoholism
- drug dependence.
- any heart defects (e.g., structural cardiac abnormality)
- family history of sudden death or irregular heartbeat
- 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)
- 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 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 Rubifen in this case. Rubifen may affect your developing baby if you take it while you are pregnant. The active ingredient in Rubifen can pass into the breast milk. Breast- feeding is not recommended.

If you have not told your doctor about any of the above, tell them before you or your child start using Rubifen.

Taking other medicines

Tell your doctor if you/your child are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket, or health food shop. You should also tell any health professional who is prescribing a new medication for you/ your child that you are taking Rubifen.

Some medicines may interfere with Rubifen. These include:

- medicines that increase blood pressure
- medicines used to treat high blood pressure like clonidine.
- medicines used to prevent blood clots like warfarin or oral anticoagulants.
- medicines for epilepsy (fits)
- medicines for depression, such as tricyclic antidepressants and MAO inhibitors
- phenylbutazone
- guanethidine.
- anaesthetics
- dopaminergic medicines used to treat Parkinson's disease or psychosis) that influence the level of dopamine in the body.
- medicines that raise the level of serotonin in the body, for example sertraline and venlafaxine used to treat depression.

These medicines may be affected by Rubifen or may affect how well it works. You or your child may need different amounts of your medicine, or you or your child may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Rubifen.

How to take Rubifen

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

These directions 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

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.

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.

When to take it

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

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 behaviour 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 tablets with the immediate release tablets to achieve the best results. The effects of the slow-release tablets are maximised when taken with a meal. Check carefully with your doctor when and how to take this combination.

If you find that this medicine keeps you or your child from sleeping, talk to your doctor about the best time to take the last dose of the day.

How long to take it

Continue taking Rubifen for as long as your doctor tells you to.

Rubifen helps to control your or your child's symptoms, but it 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.

During treatment for ADHD, Rubifen is usually stopped every so often (e.g., over weekends, school holidays and long vacation) 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 Rubifen for a long time.

If you forget to take it

Take the dose as soon as you remember. Then make sure to wait the same amount of time as usual before you 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 having an unwanted side effect may be increased.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital if you think that you or anyone else may have taken too much Rubifen.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include vomiting, agitation, headache, tremors, muscle twitching, irregular heartbeat, flushing, fever, sweating, dilated pupils, breathing problems, confusion, and seizures.

While you are using Rubifen

Things you must do

Take Rubifen exactly as your doctor has prescribed.

Like all stimulants, Rubifen may become habit-forming and can be abused by some people. If you/ 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 your doctor's appointments so that your progress can be checked.

Your doctor will want to check your blood pressure 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 Rubifen may need to be interrupted.

If you become pregnant while taking Rubifen, 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 Rubifen.

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

Things you must not do

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

If you/ your child suddenly stops 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 Rubifen is too strong or too weak, talk to your doctor.

Do not drink alcohol while you are taking Rubifen.

Drinking alcohol during treatment with Rubifen is not recommended because alcohol can worsen some of the unwanted effects of Rubifen such as dizziness and drowsiness.

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

Do not give Rubifen to anyone else, even if they have the same condition as you.

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 Rubifen until you know how it affects you.

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

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

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

To avoid the chance of a sudden rise in blood pressure during the operation. Rubifen should not be taken on the day of your/ your child operation if a certain type of anaesthetic is used.

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

Side Effects

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

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 adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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

- nausea (feeling sick), vomiting or stomach pain.
- loss of appetite
- dry mouth
- stomach upset (indigestion)
- constipation or diarrhoea
- loss of weight and slower growth in children
- constant "flu-like" symptoms such as chills, fever, sore throat and hoarse/ loss of voice, runny nose, cough, swollen glands, aching muscles, or joints
- feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose, and loss of the sense of smell
- painful and/ or swollen joints
- aching muscles, muscle tightness, spasm, tenderness, or weakness, not caused by exercise.
- muscle cramps
- excessive teeth grinding (bruxism)
- spasms of the jaw muscles that makes it difficult to open the mouth.
- fast or abnormal heartbeat
- increased blood pressure
- chest pain
- chest discomfort
- low white blood cell count
- low platelet count
- decreased sex drive
- feeling very tired or weak
- headache
- trouble sleeping
- dizziness
- drowsiness
- feeling jittery

- stuttering
- bedwetting in children at night
- unusual hair loss or thinning of the hair.
- excessive sweating
- visual disturbance
- blurred vision or problems focussing your eyes.
- dilated pupils

Stomach upset, loss of appetite and difficulty sleeping are common, especially at the start of treatment. Your doctor can usually help to reduce these symptoms by lowering the dose of Rubifen or changing the times when the tablets are taken.

Tell your doctor immediately if you notice any of the following:

- signs of allergy such rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body
- 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.
- weakness or paralysis of limbs or face, difficulty speaking, or unexplained fainting.
- unusual bleeding or bruising
- unusual tiredness, shortness of breath when exercising, dizziness, pale skin.
- uncontrollable twitching, jerking or writhing movements.
- convulsions, fits or seizures 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
- severe or persistent headache
- Thoughts or attempts of killing yourself (suicidal ideation or attempt, including completed suicide)
- confusion, delusions, or hallucinations (seeing or feeling things that are not there)
- disorientation
- mood swings, overexcitement over-activity and uninhibited behaviour
- feeling depressed, tense and/or aggressive
- feeling nervous, agitated, or irritable.
- brief periods of acute anxiety where symptoms being suddenly and usually include difficulty breathing, chest pains, fast heart rate, dizziness and light-headedness, sweating, trembling and faintness.
- restlessness or unable to sleep.
- movements or sounds that you cannot control (tics)
- muscle twitching
- numbness and tingling feeling in fingers and toes. feeling cold, tingling, and changing colour (from white to blue, then red) when cold.
- prolonged and painful erections
- difficulty getting and keeping an erection.
- enlarged breasts in boys or men.

- nose bleeds
- slowing of growth (height and weight) in children
- blockage of the oesophagus, stomach, small or large intestine in patients who already have a narrowing in any of these organs.
- increased levels of the liver enzyme ALT

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using Rubifen

Storage

- Keep your tablets in the original container until it is time to take them.
- Store the tablets in a cool dry place. Store below 25°C.
- Do not store Rubifen or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines. Rubifen 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 meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Rubifen or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Rubifen 5 mg comes as a round white scored tablet with slightly bevelled edges, marked RU-5

Rubifen 10 mg comes as a round white scored tablet with slightly bevelled edges, marked RU-10.

Rubifen 20 mg comes as a round white scored tablet with slightly bevelled edges, marked RU-20

Rubifen SR 20mg: An oblong white or white-cream smooth tablet containing 20mg methylphenidate in a modified release formulation.

Ingredients

Each Rubifen tablets contains 5 mg, 10 mg, or 20 mg of methylphenidate hydrochloride as the active ingredient. They also contain:

- Microcrystalline cellulose
- Maize starch
- Calcium hydrogen phosphate dihydrate
- Magnesium stearate

Rubifen SR tablets contains 20 mg of methylphenidate hydrochloride as the active ingredient. Each tablet also contains:

- Cetyl alcohol,
- Ethyl cellulose
- Anhydrous lactose
- Magnesium stearate,
- Opadry Y-1-700 (containing hydroxypropyl methylcellulose, polyethylene glycol 400, titanium dioxide (E-171))

RUBFEN does not contain gluten or sucrose.

Sponsor Details

Rubifen is supplied in New Zealand by: AFT Pharmaceuticals Ltd.
PO Box 33-203
Takapuna Auckland
Ph: 0800 423 823 or 09 488 0232
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