

Rubifen 10 mg immediate release tablets

Rubifen SR 20 mg slow release tablets

methylphenidate hydrochloride

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. 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.

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 take Rubifen

When you must not take it

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

- periods of severe anxiety, tension or agitation
- tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics
- Tourettes's syndrome or you have a family history of this disorder
- glaucoma (increased pressure in the eye)
- an overactive thyroid
- an irregular heartbeat
- severe angina (chest pain).

If you are not sure whether any of the above medical conditions apply to you, 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 start to take it

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

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

- severe depression or other mental illness
- epilepsy (seizures or fits)
- high blood pressure
- alcoholism
- drug dependence.

Your doctor may want to take special precautions if you 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. It is not known if the active ingredient in Rubifen passes into the breast milk. Breast-feeding is not recommended.

If you have not told your doctor about any of these things, tell him/her before you take Rubifen.

Taking other medicines

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

Other medicines and Rubifen may interfere with each other. Some of these medicines include:

- medicines that increase blood pressure
- warfarin, a medicine used to prevent blood clots
- medicines for epilepsy (fits)
- medicines for depression, such as tricyclic antidepressants and MAO inhibitors
- phenylbutazone
- guanethidine.

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have 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 from sleeping, talk to your doctor about the best time to take the last dose of the day.

How to take it

Take the tablets with a full glass of water or other liquid. If the tablets upset your stomach, you can take them with food. Always take the tablets in the same way (e.g. always with food or always without food). That way the effect will always be the same.

Take RUBIFEN only when prescribed by your doctor.

For children (6 years and over) the dose is one 5mg tablet once or twice daily (e.g. at breakfast and lunch) with weekly increases of 5-10mg. The total daily dosage should be taken in divided doses.

For adults the average daily dose is 20-30mg, taken in 2-3 divided doses. If you are unable to sleep when taking RUBIFEN late in the day, you should take the last dose before 6p.m.

Rubifen SR tablets must be swallowed whole and never crushed or chewed. Rubifen SR tablets should not be split or divided like an immediate release tablet.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How long to take it

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

Rubifen helps to control your symptoms but it does not cure your condition. Your doctor will check your 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 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.

If you take too much (Overdose)

Immediately telephone your doctor or National Poisons Information Centre, Dunedin (telephone 0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department 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.

Keep the telephone numbers for these places handy.

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 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 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 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 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 are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Rubifen.

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

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 Rubifen to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem to be 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 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.

Be careful when drinking 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.

Side effects

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

Do not be alarmed by this list 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 side effects and they worry you:

- nausea (feeling sick), vomiting or abdominal 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.

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 as swelling of the face, lips or tongue; shortness of breath, wheezing or troubled breathing
- rash, itching, red blotches, blisters or peeling of the skin
- sudden increase in body temperature, sweating, fast heart beat, 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)
- pain or tightness in the chest
- fast or irregular heart beat, changes in blood pressure
- yellow colour to the skin or eyes, dark coloured urine or light coloured bowel motions
- confusion or hallucinations (seeing or feeling things that are not really there)
- severe or persistent headache.

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

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After taking 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 window sills.

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

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

Ingredients

Rubifen tablets contain 10 mg of methylphenidate hydrochloride as the active ingredient. They also contain: Microcrystalline cellulose, maize starch, calcium hydrogen phosphate dihydrate and magnesium stearate.

Rubifen SR tablets contain 20mg of methylphenidate hydrochloride as the active ingredient. They also contain: Cetyl alcohol, Ethyl cellulose, anhydrous lactose, magnesium stearate, opadry Y-1-700 (containing hydroxypropyl methylcellulose, polyethylene glycol 400, titanium dioxide (E-171)).

RUBIFEN does not contain gluten or sucrose

Supplier

Rubifen is supplied in New Zealand by:
AFT Pharmaceuticals Ltd.
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This leaflet was prepared on 13 September 05