

Rubifen LA

methylphenidate hydrochloride

10, 20, 30, 40 and 60 mg capsules

Consumer Medicine Information (CMI)

This leaflet answers some common questions about Rubifen LA capsules.

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.

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.

1. What Rubifen LA is used for?

Rubifen LA contains the active ingredient methylphenidate hydrochloride. Methylphenidate hydrochloride is a central nervous system stimulant.

Rubifen LA capsules are used to treat Attention Deficit Hyperactivity Disorder (ADHD) or hyperkinetic disorder, 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.

Adults with ADHD often find it hard to concentrate. They often feel restless, impatient, inattentive and become bored easily. They may have difficulty organizing their private life and work.

Rubifen LA 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.

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.

Rubifen LA, like all medicines containing central nervous system stimulants, will be given to you only under close medical supervision and after diagnosis. 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 Rubifen LA use in children under 6 years old.

Note: Rubifen LA is a Controlled Drug B2.

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

2. Before you take Rubifen LA

When you must not take it

Do not take Rubifen LA if you are allergic (hypersensitive) 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 Rubifen LA if you 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, an irregular heartbeat, severe angina (chest pain), 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
- 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, check with your doctor.

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

Taking Rubifen LA 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 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.

When you must not 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 or behaviours:

- any heart defects (e.g. structural cardiac abnormality)
- tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics
- a 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)
- severe depression, bipolar disorder or other mental illness
- suicidal thoughts or behaviour
- epilepsy (seizures, convulsions, or fits)
- high blood pressure
- history of alcohol, drug abuse or drug dependence
- 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

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

Rubifen LA 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 Rubifen LA.

The active ingredient in Rubifen LA can pass into the breast milk.

3. 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.

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

- medicines that increase blood pressure
- oral anticoagulants or warfarin (medicines used to prevent blood clots)
- alpha 2 agonists like clonidine (used to treat high blood pressure)
- medicines for depression, such as tricyclic antidepressants and monoamine oxidase inhibitors (MAO inhibitors)
- some anticonvulsants (medicines used to treat epilepsy or fits)
- 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 may need to take different amounts of your medicines or you 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 start taking this medicine.

4. How to take Rubifen LA?

Your doctor will decide on the most suitable dosage according to the individual patient's medical need and response.

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

Rubifen LA is available in long-acting capsules containing 10 mg, 20 mg, 30 mg, 40 mg or 60 mg of methylphenidate hydrochloride as the active ingredient.

Your doctor will usually start with a low dose and, if necessary, increase it gradually at weekly intervals up to 20 mg to 40 mg each day.

Do not exceed the maximum recommended dose.

In children, the maximum recommended dose is 60 mg each day. In adults, the highest recommended daily dose is 80 mg.

How to take it

You can take Rubifen LA with or without food.

Swallow the capsules whole as a single dose in the morning with a full glass of water. Do not crush or chew the capsules.

If you have trouble swallowing the capsules, you can carefully open them and sprinkle the contents (little beads) over a small amount of soft food (e.g. apple sauce).

The soft food should not be warm as this could affect the special properties of the beads.

Immediately eat all of the soft food and Rubifen LA mixture. Do not store any of the soft food that has been mixed with Rubifen LA for future use.

If the capsules upset your stomach, you 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.

How long to take it

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

This medicine helps to control your symptoms but 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.

Treatment for ADHD varies in length from patient to patient. During treatment for ADHD, your doctor may stop Rubifen LA 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 forget to take a dose of Rubifen LA capsules and you remember before mid-day, take the dose as soon as you remember. Then go back to your usual schedule on the following day.

If you do not remember before mid-day, miss your dose of Rubifen LA for that day and wait until the following morning to take your next dose.

Do not take a double dose to make up for the one that you 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 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 Rubifen. 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, seizures and muscle spasms accompanied by fever and red-brown urine.

5. While you are taking Rubifen LA

Things you must do

Take Rubifen LA exactly as your doctor has prescribed.

Like all stimulants, this medicine 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 your child is not growing or gaining height or weight as expected treatment with Rubifen LA may need to be interrupted.

If you become pregnant while taking Rubifen LA, 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, dentist, or pharmacist that you are taking Rubifen LA.

Things you must not do

- Do not drink alcohol whilst you are taking Rubifen LA. Remember that some foods and medicines contain alcohol. Drinking alcohol can worsen some of the unwanted effects of this medicine, such as dizziness and drowsiness.
- 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. You will need medical supervision after having interrupted the treatment.
- Do not change the dose without talking to the doctor. If you have the impression that the effect of Rubifen LA is too strong or too weak, talk to the 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 to be alert while you are taking Rubifen LA until you know how it affects you.

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

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

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

In some patients Rubifen LA 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 Rubifen LA or changing the times when the capsules are taken.

If you experience abnormally sustained or frequent and painful erections of the penis on Rubifen LA 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 Rubifen LA 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 Rubifen LA and these medicines and tell your doctor immediately.

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

You should not take Rubifen 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.

6. Side effects

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

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 focusing 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 as Rubifen LA:

- 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 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

- 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 heart beat, 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.

7. After taking Rubifen LA

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 Rubifen LA 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.

8. Product details

What the capsules look like

Rubifen LA 10 mg modified release capsules:

Hard gelatin capsule size 2, with a dark yellow opaque cap and a white opaque body, imprinted with "RUB" in red ink on the cap and "M10" in red ink on the body, containing 10 mg white and whitish pellets.

Rubifen LA 20 mg modified release capsules:

Hard gelatin capsule size 2, white opaque capsule, imprinted with "RUB" in red ink on the cap and "M20" in red ink on the body, containing 20 mg white and whitish pellets.

Rubifen LA 30 mg modified release capsules:

Hard gelatin capsule size 2, ivory opaque capsule, imprinted with "RUB" in red ink on the cap and "M30" in red ink on the body, containing 30 mg white and whitish pellets.

Rubifen LA 40 mg modified release capsules:

Hard gelatin capsule size 1, dark yellow opaque, imprinted with "RUB" in red ink on the cap and "M40" in red ink on the body, containing 40 mg white and whitish pellets.

Rubifen LA 60 mg modified release capsules:

Hard gelatin capsule size 0, with a dark yellow opaque cap and an ivory opaque body, imprinted with "RUB" in red ink on the cap and "M60" in red ink on the body, containing 60 mg white and whitish pellets.

Ingredients

The capsules contain methylphenidate hydrochloride as the active ingredient. The capsules also contain:

Rubifen LA 10 mg modified release capsules:

Povidone
 Surinerts sugar spheres (sucrose and maize starch)
 Purified talc
 Methacrylic acid copolymer
 Ammonio methacrylate copolymer
 Triethyl citrate
 Gelatin (from bovine bones)
 Titanium dioxide
 Iron oxide yellow
 Red ink (shellac, propylene glycol, iron oxide red, strong ammonia solution, potassium hydroxide)

Rubifen LA 20 mg modified release capsules:

Povidone
 Surinerts sugar spheres (sucrose and maize starch)
 Purified talc
 Methacrylic acid copolymer
 Ammonio methacrylate copolymer
 Triethyl citrate, gelatin (from bovine bones)
 Titanium dioxide
 Red ink (shellac, propylene glycol, iron oxide red, strong ammonia solution, potassium hydroxide)

Rubifen LA 30 mg modified release capsules:

Povidone
 Surinerts sugar spheres (sucrose and maize starch)
 Purified talc
 Methacrylic acid copolymer
 Ammonio methacrylate copolymer
 Triethyl citrate
 Gelatin (from bovine bones)
 Titanium dioxide
 Iron oxide yellow, red ink (shellac, propylene glycol, iron oxide red, strong ammonia solution, potassium hydroxide)

Rubifen LA 40 mg modified release capsules:

Povidone
Surinerts sugar spheres (sucrose and maize starch)
Purified talc
Methacrylic acid copolymer
Ammonio methacrylate copolymer
Triethyl citrate
Gelatin (from bovine bones)
Titanium dioxide
Iron oxide yellow
Red ink (shellac, propylene glycol, iron oxide red, strong ammonia solution, potassium hydroxide)

Rubifen LA 60 mg modified release capsules:

Povidone
Surinerts sugar spheres (sucrose and maize starch)
Purified talc
Methacrylic acid copolymer
Ammonio methacrylate copolymer
Triethyl citrate
Gelatin (from bovine bones)
Titanium dioxide
Iron oxide yellow
Red ink (shellac, propylene glycol, iron oxide red, strong ammonia solution, potassium hydroxide)

Sponsor

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