### Rubifen LA

#### **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

#### 1. Why am I using Rubifen LA?

Rubifen LA contains the active ingredient methylphenidate hydrochloride. Rubifen LA is used to treat Attention Deficit Hyperactivity Disorder (ADHD).

For more information, see Section 1. Why am I using Rubifen LA? in the full CMI.

#### 2. What should I know before I use Rubifen LA?

Do not use if you have ever had an allergic reaction to Rubifen LA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Rubifen LA? in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with Rubifen LA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

#### 4. How do I use Rubifen LA?

- Your doctor will decide on the most suitable dosage according to the individual patient's medical need and response.
- Rubifen LA should be taken orally once daily in the morning with a full glass of water.

More instructions can be found in Section 4. How do I use Rubifen LA? in the full CMI.

#### 5. What should I know while using Rubifen LA?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using Rubifen LA.</li> <li>Be sure to keep all of your doctor's appointments so that your or your child's progress can be checked.</li> </ul>
Things you should not do	<ul> <li>Do not stop using this medicine suddenly. You will need medical supervision after having interrupted the treatment.</li> <li>Do not change the dose without talking to the doctor.</li> </ul>
Driving or using machines	<ul> <li>Rubifen LA may cause hallucinations, dizziness, drowsiness, blurred vision or other central nervous system side effects which can affect concentration in some.</li> <li>If you have any of these symptoms, do not drive, use machines or do anything else that needs quick reactions or could be dangerous.</li> </ul>
Drinking alcohol	<ul> <li>Do not drink alcohol whilst you are taking Rubifen LA.</li> <li>Remember that some foods and medicines contain alcohol.</li> </ul>
Looking after your medicine	<ul> <li>Store below 25 °C.</li> <li>Keep your medicine in the original container until it is time to take a dose.</li> </ul>

For more information, see Section 5. What should I know while using Rubifen LA? in the full CMI.

#### 6. Are there any side effects?

<u>Serious side effects:</u> sore throat, fever, chills, severe allergic reaction, bruising, suicidal thoughts/attempts, hallucinations, convulsions, twitching, fits, migraine, chest pain, fast heartbeat, skin blisters/itching, red blotches on skin, cold hands/fingers and feet/toes. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** 

<u>Common side effects:</u> runny nose, feeling nervous/anxious/depressed/aggressive/restless, excessive emotional distress/excitement, teeth grinding, jittery, headache, sleepiness, dizziness, blurry vision, abnormal heartbeat, cough, stomach complaints, appetite and/or weight decrease, hair loss, skin rash, muscle/joint pains, bedwetting (children). **Speak to your doctor if you have any of these less serious side effects and they worry you.** 

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: DRUG DEPENDENCE – Rubifen LA should be used cautiously by patients with a history of drug dependence or alcoholism. Ongoing overuse of Rubifen LA can lead to a tolerance. Your mental wellbeing might also be affected, varying in severity. Withdrawal from Rubifen LA overuse should only take place under careful supervision. If Rubifen LA is withdrawn after being used for its intended purposes, underlying symptoms of the disorder might be noticed and may require follow up by your doctor.

### **Rubifen LA**

Active ingredient(s): methylphenidate hydrochloride

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Rubifen LA. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rubifen LA.

#### Where to find information in this leaflet:

- 1. Why am I using Rubifen LA?
- 2. What should I know before I use Rubifen LA?
- 3. What if I am taking other medicines?
- 4. How do I use Rubifen LA?
- 5. What should I know while using Rubifen LA?
- 6. Are there any side effects?
- 7. Product details

#### 1. Why am I using Rubifen LA?

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

Rubifen LA modified release capsules are used to treat Attention Deficit Hyperactivity Disorder (ADHD). Rubifen LA is a stimulant, that increases attention and decreases impulsiveness and hyperactivity in patients with ADHD. 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.

Rubifen LA should be given as part of a total treatment program for ADHD that may include other measures (psychological, educational and social). It is not intended for use in patients who have symptoms due to environmental factors and/or other primary psychiatric disorders, including psychosis.

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 Rubifen LA for you or your child for another purpose. Like all medicines containing central nervous system stimulants, Rubifen LA will be given to you only under close supervision and after diagnosis.

This medicine is available only with a doctor's prescription.

# 2. What should I know before I use Rubifen LA?

#### Warnings

#### Do not use Rubifen LA if:

- you are allergic to methylphenidate hydrochloride, or any of the 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
- Always check the ingredients to make sure you can use this medicine.
- 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
  - tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics
  - increased pressure in the eye (glaucoma)
  - an overactive thyroid (hyperthyroidism) 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, which can cause pain in the arms and legs)
  - severe depression or other mental illness
  - a tumour of the adrenal gland, which sits near the kidney (pheochromocytoma).

Use Rubifen LA with caution if you have a known dependence or alcoholism.

#### Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition, especially
  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 case a serious reaction with a sudden
  increase in body temperature, extremely high blood
  pressure and severe convulsions

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Special precautions

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

- any heart defects (e.g. structural cardiac abnormality)
- a family history of sudden death and/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
- epilepsy (seizures, convulsions, or fits)
- · high blood pressure
- history of alcohol or drug abuse or dependence
- acute mental disorders that cause abnormal thinking and perceptions (psychosis) or feeling unusually excited, over-active and uninhibited (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
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon').

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

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Rubifen LA is not to be used during breastfeeding. The active ingredient in Rubifen LA can pass into the breast milk.

#### Paediatric use

• Do not use Rubifen LA in children under 6 years of age.

#### 3. What if I am taking other medicines?

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

### Some medicines may interfere with Rubifen LA and affect how it works, and include:

· medicines that increase blood pressure

- alpha-2 agonists like clonidine (used to treat high blood pressure)
- medicines used to treat depression, such as tricyclic antidepressants and monoamine oxidase inhibitors (MAO inhibitors)
- some anticonvulsants (medicines used to treat epilepsy or fits)
- oral anticoagulants or warfarin (medicines used to prevent blood clots)
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Rubifen LA.

#### 4. How do I use Rubifen LA?

#### How much to take

- Rubifen LA is available in modified release capsules containing 10 mg, 20 mg, 30 mg, 40 mg or 60 mg of methylphenidate hydrochloride as the active ingredient
- Your doctor will decide on the most suitable dosage according to the individual patient's medical need and response. Treatment 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 daily dose is 60 mg
- In adults, the maximum recommended daily dose is 80 mg
- 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.

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.

#### When to take Rubifen LA

• Rubifen LA should be taken orally once daily in the morning with a full glass of water.

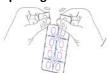
#### How long to take Rubifen LA

- Continue taking Rubifen LA until your doctor tells you to stop.
- Rubifen LA 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.

#### Administration

- Rubifen LA capsules may be taken with or without food
- Rubifen LA capsules and/or their contents should not be crushed, chewed or divided
- 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) to ensure the effect will always be the same
- Rubifen LA may be swallowed as whole capsules or the capsule contents (beads) may be sprinkled on a small amount of soft food (e.g. applesauce) (see specific instructions below).

#### **Opening instructions:**







- Do not push the capsule out of the blister cavity, as this will crush it
- Pull off a single dose by tearing along the perforated line on the blister and peel back the foil on the blister to expose the capsule.

#### **Sprinkling Rubifen LA capsule contents on food:**

- Carefully open the Rubifen LA capsule(s) and sprinkle the beads over a small amount of soft food (e.g. applesauce)
- The soft food should not be warm, since it might affect the way Rubifen LA works
- All of the mixture of Rubifen LA and soft food should be swallowed immediately and should not be chewed
- Do not store the Rubifen LA and food mixture to be used later.

#### If you forget to take Rubifen LA

Rubifen LA should be used regularly at the same time each day.

If you forget to take a dose of Rubifen LA and you remember before midday, 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 midday, 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 dose you missed.

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

#### If you use too much Rubifen LA

If you think that you have used too much Rubifen LA, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using Rubifen LA?

#### Things you should do

#### Take Rubifen LA exactly as your doctor has prescribed it.

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 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 Rubifen LA may need to be interrupted.

#### Call your doctor straight away if you:

 become pregnant while taking Rubifen LA; 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 LA.

Remind any doctor, dentist or pharmacist who treats you that you are using Rubifen LA.

#### Things you should not do

• Do not stop using Rubifen LA suddenly.

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 you doctor.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give Rubifen LA to anyone else, even if their condition seems similar to yours.

#### Drug testing in sports

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

#### **Undergoing an operation**

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

There is a chance of a sudden rise in blood pressure during the operation if an anaesthetic is used. Your doctor will advise if you/your child should take Rubifen LA on the day of the operation.

#### Painful erection

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.

#### Serotonin syndrome

- 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.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Rubifen LA affects you.

Rubifen LA may cause hallucinations, 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.

#### **Drinking alcohol**

#### Tell your doctor if you drink alcohol.

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

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

#### Looking after your medicine

• Store below 25 °C.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your medicine in the original container until it is time to take a dose.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- · in the car or on window sills.

Keep it where young children cannot reach it.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

#### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

#### Less serious side effects

Less serious side effects	What to do
Infection-related: • sore throat and runny nose  Mental health-related: • nervousness • troubled sleep or restlessness, difficulty falling asleep, sleep disturbance, sleepiness • feeling anxious, agitated • excessive emotional distress or excitement • feeling depressed • feeling aggressive • excessive teeth grinding • unusually active mood	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
ongoing depressed mood  Nervous system-related:     feeling jittery     involuntary shaking of the body (sign of tremor)     uncontrolled speech and body movements (Tourette's syndrome)     headache     dizziness	Speak to your doctor if you have any of these less serious side effects and they worry you.
Eye-related: • blurred vision or problems focusing your eyes	
Heart-related: • abnormal heart rhythm • palpitations (racing/pounding heart) • chest pain	
Respiratory-related: • cough	
Gastrointestinal-related:  nausea (feeling sick)  dry mouth  vomiting, stomach pain, upset stomach, indigestion, toothache  loss of appetite, decreased weight  loss of weight and slower growth in children	
Skin-related:	
<ul> <li>fever</li> <li>scalp hair loss</li> <li>skin rash, itchy rash and hives</li> <li>excessive sweating</li> </ul>	
<ul> <li>Muscle-related:</li> <li>joint pain</li> <li>spasm of jaw muscles that makes it difficult to open the mouth</li> <li>muscle cramps</li> </ul>	
Urinary-related: • bedwetting in children during the night	

#### Serious side effects:

Serious side effects	What to do
Infection-related: • sore throat and fever or chills	Call your doctor straight away,
Immune system-related: • severe allergic reaction (swelling of the face, lips or tongue)  Blood-related: • bruising	or go straight to the Emergency
	Department at your nearest hospital if you
Mental health-related: • thoughts or attempts of killing yourself (suicidal ideation or	notice any of these serious side effects.

Serious side effects	What to do
attempt [including completed suicide])  • seeing or feeling things that are not really there (hallucinations)  Nervous system-related:  • sudden high fever, severe convulsions  • uncontrollable twitching, jerking  • fits (seizures, convulsions, epilepsy)  • severe headache or confusion, weakness or paralysis of limbs or face, difficulty in speaking	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
<ul> <li>onset or increase in sudden twitches, movements or sound, stuttering</li> <li>rapid or slow involuntary movements of the fingers or toes which are irregular, nonrhythmic and purposeless</li> </ul>	
<ul><li>Heart-related:</li><li>fast heartbeat, chest pain</li></ul>	
Skin-related: • skin blisters or itching • red blotches on the skin	
<ul> <li>Blood vessel-related:</li> <li>fingers and toes feeling numb, cold, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon), cold hands and feet</li> </ul>	

# Other side effects from spontaneous reports and literature cases

Other side effects	What to do
Reproductive system-related: • prolonged erection of the penis (priapism)	Speak to your doctor if any of these side effects occur or if you notice anything else that is making you feel unwell.
Mental health-related:  • stammering or stuttering when speaking  • thinking about or attempting suicide (including completed suicide)	
Urinary-related: • inability to control urinating	

The frequency of these side effects is not known.

# Other side effects that occurred with medicines containing the same drug substance of Rubifen LA

Other side effects	What to do
Immune system-related: • swelling of the ears (a symptom of allergic reaction)  Mental health-related: • feeling irritated, mood changes, abnormal behaviour or thinking, anger, excessive awareness of surroundings, feeling over-active and uninhibited (mania), feeling disorientated, changes in sex drive, lack of feeling or emotion, doing things over and over again, being	Speak to your doctor if any of these side effects occur or if you notice anything else that is making you feel unwell.
obsessed with one thing, confusion, addiction  Nervous system-related:	
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	
Eye-related: • double vision, dilated pupils, trouble seeing	
Heart-related: • stopped heartbeat, heart attack	
Respiratory-related: • sore throat, shortness of breath	
Gastrointestinal-related:  • diarrhoea, constipation	
Skin-related: • swelling of the face and throat, redness of the skin, large red blotches on the skin appearing within a few hours of taking the medicine	
Muscle-related: • muscle pain, muscle twitching	
Urinary-related:  • blood in the urine, inability to control urinating	
Breast-related: • swelling of breasts in men	
General: • chest pain, tiredness, sudden death	
Investigations: • abnormal sounds from the heart	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

#### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

#### 7. Product details

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

#### What Rubifen LA contains

Methylphenidate hydrochloride
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 (10 mg, 30 mg, 40 mg and 60 mg capsules only)
Red ink, consisting of: - shellac - propylene glycol - iron oxide red - strong ammonia solution - potassium hydroxide

Do not take this medicine if you are allergic to any of these ingredients.

#### What Rubifen LA looks like

#### Rubifen LA 10 mg:

Rubifen LA 10 mg modified release capsules are provided in hard gelatin capsules (size 2) with dark yellow opaque caps and white opaque bodies, imprinted with "RUB" in red ink on the caps and "M10" in red ink on the bodies.

Each capsule contains 10 mg white and whitish pellets. Capsules are packed in perforated opaque white PVC/Aclar-PET/Alu foil peelable child-resistant blister packs of 30; all blisters are packed into an outer carton.

#### Rubifen LA 20 mg:

Rubifen LA 20 mg modified release capsules are provided in hard gelatin capsules (size 2) with white opaque caps and bodies, imprinted with "RUB" in red ink on the caps and "M20" in red ink on the bodies.

Each capsule contains 20 mg white and whitish pellets. Capsules are packed in perforated opaque white PVC/Aclar-PET/Alu foil peelable child-resistant blister packs of 30; all blisters are packed into an outer carton.

#### Rubifen LA 30 mg:

Rubifen LA 30 mg modified release capsules are provided in hard gelatin capsules (size 2) with ivory opaque caps and bodies, imprinted with "RUB" in red ink on the caps and "M30" in red ink on the bodies.

Each capsule contains 30 mg white and whitish pellets. Capsules are packed in perforated opaque white PVC/Aclar-PET/Alu foil peelable child-resistant blister packs of 30; all blisters are packed into an outer carton.

#### Rubifen LA 40 mg:

Rubifen LA 40 mg modified release capsules are provided in hard gelatin capsules (size 1) with dark yellow opaque caps and bodies, imprinted with "RUB" in red ink on the caps and "M40" in red ink on the bodies.

Each capsule contains 40 mg white and whitish pellets. Capsules are packed in perforated opaque white PVC/Aclar-PET/Alu foil peelable child-resistant blister packs of 30; all blisters are packed into an outer carton.

#### Rubifen LA 60 mg:

Rubifen LA 60 mg modified release capsules are provided in hard gelatin capsules (size 0) with dark yellow opaque caps and ivory opaque bodies, imprinted with "RUB" in red ink on the caps and "M60" in red ink on the bodies.

Each capsule contains 60 mg white and whitish pellets. Capsules are packed in perforated opaque white PVC/Aclar-PET/Alu foil peelable child-resistant blister packs of 30; all blisters are packed into an outer carton.

#### Australian Registration Number:

Rubifen LA 10 mg: AUST R 362233 Rubifen LA 20 mg: AUST R 362231 Rubifen LA 30 mg: AUST R 362232 Rubifen LA 40 mg: AUST R 362230 Rubifen LA 60 mg: AUST R 362234

#### Who distributes Rubifen LA

AFT Pharmaceuticals Pty Ltd 113 Wicks Road North Ryde NSW 2113 AUSTRALIA

Email: <a href="mailto:customer.service@aftpharm.com">customer.service@aftpharm.com</a>
Freephone (AU): 1800 AFTPHARM (1800 238 74276)

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