

IMATINIB RBX

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.

1. Why am I using IMATINIB RBX?

IMATINIB RBX contains active ingredient imatinib (as mesilate). IMATINIB RBX is used to treat adults and children/adolescents who have certain types of cancer and leukemia.

For more information, see Section [1. Why am I using IMATINIB RBX?](#) in the full CMI.

2. What should I know before I use IMATINIB RBX?

Do not use if you have ever had an allergic reaction to IMATINIB RBX 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 IMATINIB RBX?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, vitamins or supplements. Some medicines may interfere with IMATINIB RBX 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 IMATINIB RBX?

- Your doctor will tell you exactly how many tablets of IMATINIB RBX to take
- Follow the instructions provided and use IMATINIB RBX until your doctor tells you to stop

More instructions can be found in Section [4. How do I use IMATINIB RBX?](#) in the full CMI.

5. What should I know while using IMATINIB RBX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using IMATINIB RBX.• You may need regular blood tests and weight checks to find any side effects before they become serious.
Things you should not do	<ul style="list-style-type: none">• Do not give it to anyone else.• Do not use it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• IMATINIB RBX may cause dizziness, light-headedness or drowsiness in some people. Make sure you know how you react to it before you drive a car, operate machinery or do anything that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• There are no known interactions between IMATINIB RBX and alcohol
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in the original container until it is time to take it. Store it in a cool dry place.

For more information, see Section [5. What should I know while using IMATINIB RBX?](#) in the full CMI.

6. Are there any side effects?

For less serious side effects speak to your doctor if they worry you. For serious side effects you may need urgent medical attention so tell your doctor immediately.

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.

IMATINIB RBX

Active ingredient(s): *imatinib (as mesilate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMATINIB RBX. **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 IMATINIB RBX.**

Where to find information in this leaflet:

- [1. Why am I using IMATINIB RBX?](#)
- [2. What should I know before I use IMATINIB RBX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use IMATINIB RBX?](#)
- [5. What should I know while using IMATINIB RBX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using IMATINIB RBX?

IMATINIB RBX contains the active ingredient IMATINIB (as mesilate). IMATINIB RBX is a protein-tyrosine kinase inhibitor.

IMATINIB RBX is used to treat adults and children/adolescents who have chronic myeloid leukaemia (CML) and acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL).

CML and ALL are types of leukaemia in which an abnormal chromosome produces an enzyme that leads to uncontrolled growth of white blood cells. IMATINIB RBX kills the abnormal cells while leaving normal cells alone.

IMATINIB RBX is also used to treat adults for:

• **myelodysplastic /myeloproliferative diseases (MDS/MPD).**

These are a group of blood diseases in which some blood cells start growing out of control.

• **Aggressive systemic mastocytosis (ASM).**

It is a cancer in which certain blood cells, called "mast" cells, grow out of control.

• **Hypereosinophilic syndrome (HES) and or chronic eosinophilic leukaemia (CEL).**

These are blood diseases in which some blood cells, named "eosinophils", start growing out of control.

• **gastro-intestinal stromal tumours (GIST).**

This is a type of cancer of the stomach and bowels. This cancer affects the tissue that surrounds the stomach and

bowels and the cells grow uncontrollably.

• **dermatofibrosarcoma protuberans (DFSP).**

DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control. IMATINIB RBX works by slowing the growth of abnormal cells. IMATINIB RBX kills the abnormal cells while leaving normal cells alone.

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

2. What should I know before I use IMATINIB RBX?

Warnings

Do not use IMATINIB RBX if:

- You have ever had an allergic reaction to imatinib (the active ingredient), or 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.
- Always check the ingredients to make sure you can use this medicine.
- Do not take IMATINIB RBX after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. In that case, return the medicine to your pharmacist.

Check with your doctor if you:

- have ever had any other medical conditions or procedures:
 - kidney or liver problems
 - problems with your heart
 - you have had your thyroid gland removed
 - hepatitis B infection. As during treatment with IMATINIB RBX, hepatitis B (an infection of the liver) may become active again.

Your doctor may want to take special precautions in that case.

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?](#)

Pregnancy and breastfeeding

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

This medicine may be harmful to your unborn baby. If it is necessary for you to take it during pregnancy, your doctor will discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if the active ingredient, imatinib, passes into the breast milk. Because this medicine could affect your baby, breastfeeding is not recommended.

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 IMATINIB RBX and affect how it works. These include many medicines that are eliminated from the body through the liver:

- St. John's wort, a herbal medicine found in many products that you can buy without a prescription
- paracetamol, a medicine found in many common pain relievers and cold remedies (e.g. Panadol®, Panadeine®, Codral®, Tylenol®) which are known to be associated with liver toxicity.
- antibiotic medicines such as rifampicin, ketoconazole, erythromycin, clarithromycin, itraconazole
- antiviral medicines used to treat HIV/AIDS
- dexamethasone, a steroid medicine
- medicines for high cholesterol, such as simvastatin
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone
- warfarin, a medicine used to prevent blood clots
- some medicines used to treat mental disorders and depression
- some medicines used to treat high blood pressure and heart problems
- cyclosporine

You may need to take different amounts of these medicines or you 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 IMATINIB RBX.

4. How do I use IMATINIB RBX?

How much to take / use

- Your doctor will tell you exactly how many tablets of IMATINIB RBX to take

- Do not exceed the recommended dose prescribed by your doctor
- Follow the instructions provided and use IMATINIB RBX until your doctor tells you to stop
- Your doctor may direct you to take a higher or lower dose, depending on your response to IMATINIB RBX.
- IMATINIB RBX is usually taken as a single dose each day. However, your doctor may want you to take them in two doses, one in the morning and one in the evening.

When to take / use IMATINIB RBX

For the best effect, take IMATINIB RBX at about the same time each day.

Taking them at the same time each day will help you to remember to take them.

How to take IMATINIB RBX

Take the medicine with a large glass of water and food. This will help to avoid irritating the lining of your oesophagus (food pipe) and stomach.

If you are unable to swallow the tablets:

- Put the required tablet(s) in a glass of water or apple juice (approximately 50 ml for a 100 mg tablet and 200 ml for a 400 mg tablet).
- Stir with a spoon to completely dissolve the tablet(s).
- Immediately drink the whole contents of the glass.

How long to take it

Continue taking IMATINIB RBX every day for as long as your doctor prescribes.

Your doctor will keep a close check on you to make sure you are still benefiting from treatment.

If you forget to use IMATINIB RBX

IMATINIB RBX should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as you remember, then continue with your normal schedule.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you use too much IMATINIB RBX

If you think that you have used too much IMATINIB RBX 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.

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

5. What should I know while using IMATINIB RBX?

Things you should do

Make sure you follow your doctor's instructions carefully and keep all appointments.

You will need regular follow-up to make sure the treatment is working. Regular blood tests and weight checks can also find side effects before they become serious.

Some children and adolescents taking IMATINIB RBX may have slower than normal growth. Growth will be monitored at regular visits by your doctor.

Make sure you use a method of contraception to prevent pregnancy during treatment and for at least 15 days after stopping treatment with IMATINIB RBX

Call your doctor straight away if you:

- Become pregnant while you are taking this medicine.
- Think you might be having an allergic reaction to IMATINIB RBX

Remind any doctor, dentist or pharmacist you visit that you are using IMATINIB RBX.

Things you should not do

- Do not stop using this medicine suddenly unless your doctor tells you to
- Do not give this medicine to anyone else even if their condition seems to be the same as yours.

Drinking grapefruit juice

Avoid drinking grapefruit juice while you are being treated with IMATINIB RBX. Grapefruit juice may interact with IMATINIB RBX and affect how your body uses this medicine.

Treating a headache, cold or other minor aches and pains

Try to avoid taking medicines containing paracetamol (e.g. Panadol®, Panadeine®, Codral®, Tylenol®). Ask your pharmacist to suggest an alternative medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how IMATINIB RBX affects you.

IMATINIB RBX may cause dizziness, light-headedness or drowsiness in some people. Make sure you know how you react to it before you drive a car, operate machinery or do anything that could be dangerous.

Wear sun protection when outdoors

When you are outdoors, wear protective clothing and use at least a SPF 15+ sunscreen. Do not use a sunlamp or tanning beds

This medicine may cause your skin to be much more sensitive to sunlight than it normally is.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning tell your doctor.

Drinking alcohol

Tell your doctor if you drink alcohol.

There are no known interactions of IMATINIB RBX with alcohol.

Looking after your medicine

Storage

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

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

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.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

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
Stomach problems <ul style="list-style-type: none">• indigestion, upset stomach, wind, feeling of bloating• nausea (feeling sick) or vomiting• diarrhoea• constipation	Speak to your doctor if you have any of these less serious side effects and they worry you.

<p>Skin problems</p> <ul style="list-style-type: none"> • rash, eczema, itching, dry skin, darkening or lightening of skin • symptoms of sunburn which happens more quickly than normal <p>General problems</p> <ul style="list-style-type: none"> • dry mouth • swelling of fingers, eyelids, face or lower legs due to fluid build up (see your doctor immediately if fluid build up is severe) • swelling, aching, cramping or stiffness in joints or muscles • pain after stopping IMATINIB RBX (including muscle, limb, joint, bone and back pain) • pain in the bones or along veins • headache, dizziness, light-headedness or vertigo (spinning sensation) • tiredness, weakness, feeling generally unwell • numbness, coldness or tingling in fingers and toes • difficulty sleeping, feeling anxious, depressed, confused or forgetful • change in sense of taste • rash, eczema, itching, dry skin, darkening or lightening of skin • symptoms of sunburn (blistering, itchy, swelling, redness) • irritated, red, runny or itchy eyes, blurred vision • ringing in the ears • changes in appetite and weight • hair loss • sweating during the night • throat pain • cough or cold symptoms • loss of interest in sex, problems with sexual function • breast enlargement, nipple pain, painful periods • reddening and/or swelling on the palms of the hands and soles of the feet which may be accompanied by tingling sensation and burning pain • slowing of growth in children and adolescents 	
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<ul style="list-style-type: none"> • cough, difficult or painful breathing, wheezing, pain in chest when breathing • muscle weakness, muscle spasms, abnormal heart rhythm • fever, tiredness, irregular heart beat • nausea, shortness of breath, clouding of urine, joint discomfort • crushing chest pain, fever, tiredness <p>Stomach problems</p> <ul style="list-style-type: none"> • severe abdominal pain, vomiting blood, black or bloody stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain • nausea, diarrhoea, vomiting, <p>Skin problems</p> <ul style="list-style-type: none"> • weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, swollen glands, sore throat or mouth ulcers • pale skin, tiredness, breathlessness, dark urine, yellowing of your skin or eyes • severe rash, red skin, blistering of the lips, eyes, skin or mouth, skin peeling, fever, red raised or purple skin patches, itching, burning, pustular eruption • inflammation of the skin caused by an infection • blisters on skin or mouth/nose/genitals <p>General problems</p> <ul style="list-style-type: none"> • rapid weight gain, noticeable swelling (legs, face),) • pain in bone and joints • thirst, weight loss and severely decreased urine output • blood in the urine • nosebleeds or any other unusual bleeding • vision impairment, blurred vision, blood in eye • seizures (fits) • pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding • muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles • nausea, loss of appetite, dark coloured urine or yellowing of your skin or eyes • change in urine or blood in urine, pain in the kidney area, tiredness, 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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Serious side effects

Serious side effects	What to do
<p>Chest problems</p> <ul style="list-style-type: none"> • severe allergic reaction that can result in difficulty breathing dizziness. 	<p>Call your doctor straight away, or go straight to the</p>

<p>loss of appetite, nausea/vomiting, lack of concentration, headache, cramping, itching</p> <ul style="list-style-type: none"> • nausea, diarrhea, vomiting, abdominal pain, fever • severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands, stomach pain or aching joints and muscles • severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness • swelling and pain in one part of the body • severe headache, dizziness, blurred vision • fever, skin rash, joint pain and swelling as well as tiredness, loss of appetite, nausea, jaundice (yellowing of the skin), pain in the upper right abdomen, pale stools and dark urine • fatigue, dizziness, shortness of breath, bruises, gum/nose bleeds, minor cuts that bleed a lot, confusion, sleepiness, seizures, decreased urine, swollen legs, fever 	
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	(proprietary ingredient number 108518)
Potential allergens	IMATINIB RBX tablets are free from lactose and gluten.

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

What IMATINIB RBX looks like

IMATINIB RBX 100 mg tablets are dark yellow to brownish orange, film-coated, round tablets debossed with '1' and '1' on either side of break line on one side and plain on other side of the tablet. Available in blister packs of 60 tablets.

IMATINIB RBX 400 mg tablets are dark yellow to brownish orange, film-coated oval tablets debossed with '1' and '2' on either side of break line on one side and plain on other side of the tablet. Available in blister packs of 30 tablets.

Australian Register Numbers

IMATINIB RBX 100 mg tablets –
AUST R 225484 (blister), AUST R 225490 (bottle)
IMATINIB RBX 400 mg tablets –
AUST R 225491 (blister), AUST R 225483 (bottle)

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 www.tga.gov.au/reporting-problems. 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.

What IMATINIB RBX contains

Active ingredient (main ingredient)	imatinib (as mesilate)
Other ingredients (inactive ingredients)	magnesium stearate, OPADRY complete film coating system 03F565018 BROWN

Who distributes IMATINIB RBX

Sun Pharma ANZ Pty Ltd
12 Waterloo Road
Macquarie Park NSW 2113
Australia
customerservice.aus@sunpharma.com
Tel: 1800 726 229

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