

ARX-IMATINIB

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 ARX-IMATINIB?

ARX-IMATINIB contains the active ingredient imatinib. ARX-IMATINIB is used to treat leukaemia and some other forms of cancer.

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

2. What should I know before I use ARX-IMATINIB?

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

3. What if I am taking other medicines?

Some medicines may interfere with ARX-IMATINIB 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 ARX-IMATINIB?

- Your doctor will advise on the appropriate dose for your condition.
- ARX-IMATINIB is usually taken as a single dose each day, although twice daily dosing may be recommended by your doctor.
- Take ARX-IMATINIB with food and a large glass of water.
- Capsules should be taken whole. If you have trouble swallowing, capsules may be opened and poured into a glass of water or apple juice and swallowed.

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

5. What should I know while using ARX-IMATINIB?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARX-IMATINIB.• Follow your doctor's instructions carefully and keep all appointments to ensure your treatment is working.• Make sure you use a method of contraception to prevent pregnancy during treatment and for 15 days after ending treatment. Advise your doctor if you become pregnant.• Wear protective clothing and wear at least 15+ sunscreen when outdoors to minimise sun exposure.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine until advised by your doctor.• Avoid drinking grapefruit juice while you are being treated with ARX-IMATINIB.• Avoid taking medicines containing paracetamol.
Driving or using machines	<ul style="list-style-type: none">• This medicine 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">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its original packaging until it is time to take it.• Keep it in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Tell your doctor if you notice anything that is making you unwell while you are taking ARX-IMATINIB.

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.

ARX-IMATINIB

Active ingredient(s): *imatinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-IMATINIB. **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 ARX-IMATINIB.**

Where to find information in this leaflet:

- [1. Why am I using ARX-IMATINIB?](#)
- [2. What should I know before I use ARX-IMATINIB ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-IMATINIB?](#)
- [5. What should I know while using ARX-IMATINIB?](#)

7. ARE THERE ANY SIDE EFFECTS?

- [7. Product details](#)

1. Why am I using ARX-IMATINIB?

ARX-IMATINIB contains the active ingredient imatinib. ARX-IMATINIB is a protein-tyrosine kinase inhibitor used to treat leukaemia and a number of other forms of cancer by slowing the growth of abnormal cells while leaving normal cells alone.

ARX-IMATINIB 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.

ARX-IMATINIB 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) 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.

Your doctor may have prescribed it for another purpose.

There is not enough information to recommend the use of ARX-IMATINIB in children under 3 years of age for most uses. For use in CML, there is no experience with the use of ARX-IMATINIB in children below 2 years of age. For acute lymphoblastic leukaemia with Philadelphia chromosome positive (Ph-positive ALL), there is no experience with the use of ARX-IMATINIB in children below 1 year of age.

Talk to your doctor or pharmacist if you have any questions about ARX-IMATINIB.

2. What should I know before I use ARX-IMATINIB?

Warnings

Do not use ARX-IMATINIB if:

- you are allergic to imatinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

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 ARX-IMATINIB 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 ARX-IMATINIB, hepatitis B (an infection of the liver) may become active again.
- take any medicines for any other condition

Your doctor may want to take special precautions in these cases.

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?](#)

ARX-IMATINIB is not addictive.

Pregnancy and breastfeeding

Tell your 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.

Tell 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, breast-feeding 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 and ARX-IMATINIB may interfere with each other. 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. A patient, who was taking paracetamol regularly for fever, died of acute liver failure. Although the cause is currently unknown, special caution should be exercised when using paracetamol and ARX-IMATINIB.
- 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
- cyclosporin

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.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

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

4. How do I use ARX-IMATINIB?

Follow the instructions provided and use ARX-IMATINIB until your doctor tells you to stop. These instructions 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/use

For CML, the usual dose for an adult is 400 to 600 mg each day and the maximum dose is 800 mg each day. The dose depends on what stage of CML you have. For Ph-positive ALL the usual dose is 600 mg each day.

For children treated with CML and Ph-positive ALL, the dose depends on the size of the child.

For MDS/MPD, the starting dose is 400 mg.

For ASM and HES/CEL, the usual starting dose is 400 mg. For some patients the starting dose may be 100 mg.

For GIST, the usual dose is 400 mg or 600 mg each day.

For DFSP, the starting dose is 800 mg per day.

Daily dose of 400 mg should be taken as one tablet of 400 mg once a day.

Daily dose of 600 mg should be taken as either:

- six capsules of 100 mg or
- one capsule of 400 mg plus two 100 mg capsules once a day.

A daily dose of 800 mg should be taken as 400 mg twice a day, in the morning and in the evening.

Your doctor may direct you to take a higher or lower dose, or stop treatment if needed depending on your response to ARX-IMATINIB.

When to take/use ARX-IMATINIB

ARX-IMATINIB 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.

Continue taking ARX-IMATINIB 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.

How to take ARX-IMATINIB

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.

Swallow the capsules whole with a large glass of water. Do not open or crush the capsules unless you have difficulty in swallowing (e.g. in children).

- If you are unable to swallow the capsules, you can open them up and pour the powder into a glass of still water or apple juice.
- If you are a woman who is pregnant or might get pregnant and are trying to open the capsules, you should handle the contents with caution in order to avoid skin-eye contact or inhalation.

You should wash your hands immediately after opening the capsules.

For the best effect, take the medicine at about the same time each day. Taking them at the same time each day will help you to remember to take them.

If you forget to use IMATINIB

ARX-IMATINIB 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.

Do not take a double dose to make up for the one that 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 ARX-IMATINIB

If you think that you have used too much ARX-IMATINIB, 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.

Keep the phone numbers for these places handy.

5. What should I know while using ARX-IMATINIB?

Things you must 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, weight checks and urine tests can also find side effects before they become serious.

Some children and adolescents taking ARX-IMATINIB 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 with ARX-IMATINIB and for 15 days after ending treatment.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARX-IMATINIB.

Call your doctor straight away if you:

- if you become pregnant while you are taking this medicine.

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

Things you should not do

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

Do not give this medicine to anyone else even if their condition seems to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

If you need to take something to treat 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.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use sunlamps 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.

Driving or using machines

This medicine 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

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your medicine in its original packaging until it is time to take it. The medicine will not keep as well if taken out of the packaging.

Keep this medicine in a cool dry place where the temperature stays below 25°C.

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 windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking 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?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with this medicine.

All medicines have some unwanted side effects. Sometimes they are serious, but 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • swelling of fingers, eyelids, face or lower legs due to fluid build-up (see your doctor immediately if fluid build-up is severe) • indigestion, upset stomach, wind, feeling of bloating • nausea (feeling sick) or vomiting • diarrhoea • constipation • dry mouth • swelling, aching, cramping or stiffness in joints or muscles • 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 (such as redness, itching, swelling or blistering of the skin) which happens more quickly than normal • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • severe allergic reaction that can result in difficulty breathing, dizziness. • rapid weight gain, swelling of the extremities (calves, ankles), generalised swelling such as swelling of the face (signs of water retention) • weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, swollen glands, sore throat or mouth ulcers (signs of low level of blood cells) • pale skin, tiredness, breathlessness, dark urine (signs of breakdown of red blood cells). • pain and having difficulty walking • cough, difficult or painful breathing, wheezing, pain in chest when breathing (signs of lung infections/disorders). • muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood). • muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles (signs of muscle disorders) • severe abdominal pain, vomiting blood, black or bloody stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain (signs of gastrointestinal disorders) • thirst, weight loss and severely decreased urine output (signs of low intake of drinks/fluids) • nosebleeds or any other unusual bleeding • vision impairment, blurred vision, blood in eye • nausea, loss of appetite, dark coloured urine or yellowing of your skin or eyes (signs of liver disorders). • nausea, diarrhoea, vomiting, abdominal pain, fever (signs of inflammatory bowel disease). • severe rash, red skin, blistering of the lips, eyes, skin or mouth, skin peeling, fever, red raised or purple skin patches, itching, 	<p>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.</p>

burning, pustular eruption (signs of skin disorder).

- 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
- inflammation of the skin caused by an infection (sign of cellulitis)
- blood in the urine
- severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system disorder such as bleeding or swelling in the brain)
- seizures (fits)
- swelling and pain in one part of the body (signs of clots in blood vessels)
- crushing chest pain, fever, tiredness, irregular heart beat (signs of heart disorders such as heart attack, angina).
- muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood)
- pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding, (signs of gynaecological disorder)
- nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory (such as high potassium, uric acid, and phosphorous levels and low calcium levels in the blood)
- severe headache, dizziness, blurred vision (signs of increased pressure inside skull).
- 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 (potential signs of hepatitis B reactivation).
- Fatigue, dizziness, shortness of breath, bruises, gum/nose bleeds, minor cuts that bleed a lot, confusion, sleepiness, seizures, decreased urine, swollen legs, fever (potential signs of thrombotic microangiopathy).

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. Other side effects not listed here or not yet known may happen in some people. Some of these side effects can only be found by laboratory testing.

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 ARX-IMATINIB contains

Active ingredient (main ingredient)	Imatinib mesilate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• crospovidone• sodium stearyl fumarate• gelatin• water• sodium lauryl sulphate• titanium dioxide• iron oxide red• iron oxide yellow• iron oxide red (100 mg and 400 mg capsules only)• iron oxide black (400 mg capsule only)

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

What ARX-IMATINIB looks like

ARX-IMATINIB 50 mg capsules (AUST R 261059) are off-white to brownish yellow colour granular powder filled in light yellow to orange yellow opaque Size '4' Hard Gelatin capsule imprinted with 'RDY' on cap and '50' on body with red ink. Available in blister packs of 30 capsules.

ARX-IMATINIB 100 mg capsule (AUST R 261054) is an off-white to brownish yellow colour granular powder filled in an orange to greyish-orange opaque size '1' hard gelatin capsule imprinted with 'RDY' on cap and '100' on body with red ink. Available in blister packs of 60 capsules.

ARX-IMATINIB 400 mg capsule (AUST R 261060) is an off-white to brownish yellow colour granular powder filled in a very dark yellow to brownish-orange opaque size '00' hard

gelatin capsule imprinted with 'RDY' on cap and '400' on body with red ink. Available in blister packs of 30 capsules.

Who is the Sponsor of ARX-IMATINIB

Dr. Reddy's Laboratories (Australia) Pty Ltd
Level 3, 390 St Kilda Road
Melbourne, VIC 3004
Australia

Who Distributes ARX-IMATINIB

Arrotex Pharmaceuticals Pty Ltd

Cremorne VIC 3121

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