

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

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

1. Why am I using ICLUSIG?

ICLUSIG contains the active ingredient ponatinib hydrochloride. ICLUSIG is used to treat adults with certain types of leukaemia.

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

2. What should I know before I use ICLUSIG?

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

3. What if I am taking other medicines?

Some medicines may interfere with ICLUSIG 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 ICLUSIG?

- You should follow all directions on how to use ICLUSIG given by your doctor or pharmacist

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

5. What should I know while using ICLUSIG?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using ICLUSIG. If you are pregnant, intending to get pregnant or to father a child, tell your doctor immediately.
Things you should not do	Do not stop using this medicine without talking to your doctor first.
Driving or using machines	Be careful driving or operating machinery until you know how ICLUSIG affects you.
Drinking alcohol	Tell your doctor if you have a history of alcohol abuse.
Looking after your medicine	- Store the tablets in the original container to protect from light. - Keep the medicine in a cool, dry place where temperature stays below 30°C.

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

6. Are there any side effects?

Severe side effects include chest pain, shortness of breath, weakness in one side, fast or irregular heartbeats, leg or abdominal swelling, sudden weight gain, jaundice, loss of appetite, elevated blood pressure, severe headache, nausea, vomiting, severe abdominal pain, unusual bleeding or easy bruising, low blood cell counts, fever, chills. Common side effects include upper respiratory tract infection, pneumonia, skin rash, sleeplessness, dry or blurred eye, conjunctivitis, rash, dry skin, pruritus.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: The following adverse effects have been observed in some ICLUSIG-treated patients in the main clinical trial. Therefore, your medical condition will be monitored during ICLUSIG treatment with interruption or stoppage of the treatment if decided necessary by your doctor:

- Complete or partial blockage of a blood artery: occurred in ICLUSIG-treated patients in the main clinical trial, resulting in heart attack or chest pain, stroke, narrowing of blood vessels, vision loss, severe blood circulation disorder (sometimes resulting in amputation), and the need for urgent surgical procedure to widen the blocked or narrowed arteries.
- Blockage of blood vein due to a blood clot
- Heart failure
- High blood pressure including a marked proportion graded as severe
- Liver toxicities including fatal liver failure.

ICLUSIG®

Active ingredient(s): *ponatinib* (pon-a-tin-ib) *hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ICLUSIG. **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 ICLUSIG.**

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 this medicine. You can also download the most up to date leaflet from www.takeda.com/en-au. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

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

1. Why am I using ICLUSIG?

ICLUSIG contains the active ingredient ponatinib hydrochloride. ICLUSIG belongs to a group of medicines called tyrosine kinase inhibitors. In patients with CML and Ph + ALL, changes in the DNA trigger a signal that tells the body to produce abnormal white blood cells. ICLUSIG blocks this signal, thereby stopping the production of these cells.

ICLUSIG is used to treat adults with the following types of leukaemia who are no longer benefiting from treatment with other medicines:

Chronic myeloid leukaemia (CML): a blood cancer (leukaemia) involving too many abnormal white blood cells (granulocytes), in the blood and the bone marrow (where blood cells are formed)

Philadelphia-chromosome positive acute lymphoblastic leukaemia (Ph+ ALL): another type of leukaemia involving too many immature white blood cells (lymphocytes or lymphoblasts), in the blood and blood-forming bone marrow.

In both types of leukaemia, some of the DNA (genetic material) has become rearranged to form an abnormal chromosome, called the Philadelphia chromosome.

This medicine is only available with a prescription from a doctor experienced with leukaemia treatment.

2. What should I know before I use ICLUSIG?

Warnings

Do not use ICLUSIG if:

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

Check with your doctor if you have:

- a history of blood clots in your blood vessels (arteries or veins)
- heart problems, for example heart failure, irregular heartbeats, a condition called QT prolongation or a prior heart attack
- a history of stroke
- high blood pressure
- diabetes
- high cholesterol
- bleeding problems
- liver or kidney problems
- a pancreas disorder
- a history of alcohol abuse
- hepatitis B
- take any medicines for any other condition

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 your doctor if you are pregnant, intending to become pregnant or to father a child.

You and your partner must use effective contraception during your treatment with this medicine.

Women of childbearing age being treated with ICLUSIG should avoid becoming pregnant, as potential risks exist for the unborn child.

Men being treated with ICLUSIG should avoid fathering a child during treatment.

You must not breastfeed during treatment with ICLUSIG. It is not known if ICLUSIG passes into breast milk.

Your doctor can discuss with you the risks involved.

Tell your doctor if you are lactose intolerant. ICLUSIG tablets contain lactose.

If you have not told your doctor or pharmacist about any of the above, tell them before you take ICLUSIG.

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 ICLUSIG may interfere with each other. These include:

- ketoconazole, itraconazole, voriconazole: medicines used to treat fungal infections
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir: medicines used to treat HIV infection
- clarithromycin, telithromycin, troleandomycin: medicines used to treat bacterial infections
- nefazodone, a medicine to treat depression
- St. John's Wort, a herbal product used to treat depression
- carbamazepine, a medicine to treat epilepsy, euphoric/depressive stages and certain pain conditions
- phenobarbital, phenytoin: medicines used to treat epilepsy
- rifabutin, rifampicin: medicines used to treat tuberculosis or other infections
- medicines which decrease stomach acid such as omeprazole, pantoprazole, ranitidine, cimetidine, famotidine, aluminum, and magnesium hydroxides
- digoxin: a medicine used to treat heart weakness
- dabigatran: a medicine used to prevent the formation of blood clots
- colchicine: a medicine used to treat gout attacks
- pravastatin, rosuvastatin, medicines used to lower cholesterol
- methotrexate, a medicine used to treat arthritis, cancer and some skin diseases
- sulfasalazine, a medicine used to treat severe bowel and rheumatic joint inflammation.

These medicines may be affected by ICLUSIG or may affect how well it works. You may need to use different amounts of your medicine or take different medicines.

Avoid grapefruit products such as grapefruit juice, or Seville orange-based products such as marmalade.

These products may contain components that alter the metabolism of some medicines, including ICLUSIG.

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

4. How do I use ICLUSIG?

ICLUSIG should only be prescribed by a doctor experienced in leukaemia treatment.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The recommended starting dose is one 45 mg tablet once daily.

Your doctor may reduce your dose or tell you to temporarily stop taking ICLUSIG if:

- the number of white blood cells, called neutrophils, is reduced
- the number of blood platelets is reduced
- a severe side effect occurs, not affecting the blood, for example if you develop:
 - o pancreas inflammation
 - o increased levels of serum protein lipase or amylase
 - o liver inflammation and/or increased levels of liver enzymes, such as liver transaminase or bilirubin
- you develop heart or blood vessel problems.

ICLUSIG may be resumed at the same, or at a reduced dose, after the event is resolved or controlled.

Your doctor may reduce your dose of ICLUSIG if your condition has responded well to ICLUSIG.

Your doctor may recommend you discontinue ICLUSIG if your condition has not responded to the treatment at all or you cannot tolerate the treatment.

When to take ICLUSIG

Take ICLUSIG at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How to take ICLUSIG

Swallow the tablets whole with a glass of water.

Do not crush or dissolve the tablets.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

It is important to keep taking your medicine even if you feel well.

Do not stop taking ICLUSIG without talking to your doctor first.

If you forget to use ICLUSIG

ICLUSIG should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is less than 12 hours before 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 getting an unwanted side effect.

If you use too much ICLUSIG

If you think that you have used too much ICLUSIG, 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 ICLUSIG?

Things you should do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. These may include:

- checking your heart function and the condition of your arteries and veins
- checking your blood count
- measuring your serum protein known as lipase
- testing your liver function
- checking your blood pressure
- checking for hepatitis B infection.

A Patient Alert Card (PAC) is provided in the pack with your ICLUSIG tablets and should be carried with you at all times. The PAC provides important and readily accessible information for your Healthcare Practitioners on important risks, their treatment and contact details of your haematologist. If you require additional copies, please contact the supplier whose details can be found at the end of this leaflet.

Things you should not do

- Do not stop using this medicine or lower the dosage, without checking with your doctor.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful driving or operating machinery until you know how ICLUSIG affects you.

This medicine may cause dizziness, tiredness, visual impairment, mental status changes, confusion, or blurred vision in some people.

Looking after your medicine

Keep your tablets in the bottle until it is time to take them.

Store the tablets in the original container to protect from light.

Keep the medicine in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	What to do
• nausea, vomiting, constipation, diarrhoea • abdominal distension, discomfort, indigestion, pain • stomach acid reflux • rash, dry skin, itching, peeling of the skin, skin pain, infection of the skin • inflammation of hair follicles, hair loss • fatigue, sleeplessness, weakness • muscle spasms and pain, muscle weakness • hot flush/flushing, night sweats, increased sweating • decreased appetite, weight loss	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
- dehydration - dry mouth, inflammation in the mouth, bleeding gums - pins and needles, tingling or burning sensation in feet, legs, hands or arms - inability to develop or maintain an erection.	

Serious side effects

Serious side effects	What to do
- sudden severe headache - eye or sight changes (blurred vision, loss of vision, dry eye, eye pain) - eyelid or face swelling, conjunctivitis - changes in speech or difficulty talking - dizziness or feeling faint - decreased alertness, lethargy or confusion - chest pain or pressure - pain in your arms, legs, back, neck or jaw - changes in heart rate (abnormally slow, fast, or irregular heart rate), bruise or blood clot - breathing difficulties (shortness of breath, cough, rapid breathing) - weakness on one side of the body - numbness or loss of fine motor skills - trouble talking - unusual bleeding, including blood in your stool/bowel motions or dark or tarry stool, vomiting blood, bruising easily, nose bleeding - fever in association with other signs of infection, chills - yellow skin and/or eyes - severe stomach area pain, swelling due to build-up of fluid around the stomach - dark-coloured urine - swelling of the leg, ankle or foot. - painful rash, blistering, and mouth sores - signs of Posterior Reversible Encephalopathy Syndrome (PRES): ICLUSIG may trigger a condition called PRES. Call your healthcare provider right away if you experience headaches, seizures, confusion, changes in vision, problems thinking	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.

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 ICLUSIG contains

Active ingredient (main ingredient)	Ponatinib hydrochloride
Other ingredients (inactive ingredients)	lactose microcrystalline cellulose sodium starch glycollate silica - colloidal anhydrous magnesium stearate talc Macrogol 4000 poly vinyl alcohol titanium dioxide
Potential allergens	ICLUSIG does not contain gluten, sucrose, tartrazine or any other azo dyes.

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

What ICLUSIG looks like

ICLUSIG 10 mg (AUST R 374484): white to off-white, biconvex, oval film-coated tablet, marked with "NZ" on one side. Available in bottles of 30 tablets.

ICLUSIG 15 mg (AUST R 212583): white, round film-coated tablet, marked "A5" on one side. Available in bottles of 36 or 60 tablets.

ICLUSIG 30 mg (AUST R 374492): white, biconvex, round film-coated tablet, marked with "C7" on one side. Available in bottles of 30 tablets.

ICLUSIG 45 mg (AUST R 212584): white, round film-coated tablet, marked "AP4" on one side. Available in bottles of 30 tablets.

Not all strengths may be marketed.

Who distributes ICLUSIG

Takeda Pharmaceuticals
Australia Pty Ltd
Level 39, 225 George Street
Sydney NSW 2000
Australia
Phone: 1800 012 612

This leaflet was prepared in September 2022.

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