ICLUSIG®

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 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. • Keep out of reach of children.

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

6. Are there any side effects?

Common side effects: upper respiratory tract infection, anaemia, decreased appetite, sleeplessness, headache, dizziness, cough, shortness of breath, stomach pain, constipation, nausea, diarrhoea, vomiting, rash, dry skin, itching, pain in bones, joints, muscles or back, muscle spam, tiredness, fever, swelling of legs or arms, weakness, changes in blood cell levels. Serious side effects: lung infection, sudden severe headache, seizures, lethargy or confusion, problems thinking, eye or sight changes (blurred vision, loss of vision, dry eye, eye pain), eyelid or face swelling, changes in speech or difficulty talking, dizziness or feeling faint, decreased alertness, chest pain or pressure, changes in heart rate, bruise or blood clot, breathing difficulties, weakness on one side of the body, numbness or loss of fine motor skills, 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, aneurysm or artery tear.
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: The following adverse effects have been observed in some ICLUSIG-treated patients

- **Events when arteries are narrowed or blocked, including heart attack, stroke, narrowing of large blood vessels of the brain, severe blood circulation problems (sometimes resulting in amputation), loss of vision, events requiring an urgent surgical procedure to restore blood flow. Some of these events have been fatal.**
- **Blocked blood vein due to a blood clot.**
- **Heart failure, sometimes fatal.**
- **High blood pressure, including a sudden, severe increase in blood pressure.**
- **Liver toxicity, including liver failure, sometimes fatal.**

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): a 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
- a history of aneurysm or tear in a blood vessel wall
- high blood pressure
- diabetes
- high cholesterol
- bleeding problems
- a liver disorder
- kidney problems, including narrowing of the blood vessels to one or both kidneys
- a pancreas disorder
- a history of alcohol abuse
- ever had or might have hepatitis B. This is because during treatment with ICLUSIG, hepatitis B may become active again. Your doctor will check for signs of this infection before starting treatment with ICLUSIG.
- 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.

It is not known if ICLUSIG affects how contraceptive pills work. They may not work as well to prevent pregnancy when taken at the same time as ICLUSIG. Use a different or an additional method of contraception during your treatment with ICLUSIG.

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:

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

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 eating or drinking products or juices that contain grapefruit, star fruit, pomegranate, Seville oranges or similar fruit.

These products may contain components that alter the the way your body processes 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:
    - pancreas inflammation
    - increased levels of serum protein lipase or amylase
    - 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 complete blood count. This will be repeated every 2 weeks for the first 3 months after starting treatment. Afterwards, it will be performed every month or as indicated by your doctor.
- measuring your serum protein known as lipase. This will be repeated every 2 weeks for the first 2 months and then regularly afterwards.
- testing your liver function. This will be performed periodically, as indicated by your doctor.
- checking your blood pressure at every visit
- 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, blurred vision or visual impairment, mental status changes or confusion 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
• upper airway infection (may cause breathing difficulty) • nausea, vomiting, constipation, diarrhoea • abdominal distension, discomfort, indigestion, pain • stomach acid reflux • rash, dry skin, itching, painful red lumps under the skin, 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 • 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.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• pneumonia (lung infection that may cause breathing difficulty) • 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 • 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 • aneurysm (a bulge in the wall of a blood vessel including in the chest, arms, legs, heart, and brain). Symptoms will differ by the site. There can be cough, coughing up blood, strong pain high in your neck or in your back when you didn't hurt yourself, problems swallowing, hoarse voice, unusual pulsing in your chest or abdomen. • artery tear. Symptoms include sudden severe pain in the back, chest or abdomen.	**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 affects 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 monohydrate microcrystalline cellulose sodium starch glycollate colloidal anhydrous silica magnesium stearate talc Macrogol 4000 poly vinyl alcohol titanium dioxide
Potential allergens	ICLUSIG contains lactose. 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 15 mg (AUST R 212583): white, round film-coated tablet, marked "A5" on one side. Available in bottles of 30 or 60 tablets.

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

Who distributes ICLUSIG

Takeda Pharmaceuticals

Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Phone: 1800 012 612

www.takeda.com/en-au

This leaflet was prepared in September 2026.

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