

# Ponatinib

Ponatinib is a targeted treatment used for some people with chronic myeloid leukaemia (CML).

## Summary

- Ponatinib is a type of medicine called a tyrosine kinase inhibitor (TKI).
- It comes as a film-coated tablet you take every day with water. The number of tablets you need to take should be printed on the named label on the medicine packaging.
- You will have regular blood tests to check how well your CML is responding to ponatinib.
- Your haematology team will also carry out tests to check how your body is coping with ponatinib treatment.
- Side effects of ponatinib are usually mild to moderate. Some people have very few side effects, whereas other people experience more serious side effects.
- Some side effects can be serious if they are not treated promptly. Contact your haematology team straight away if you get:
  - Signs of blocked arteries and veins, like a heart attack, stroke, blurred vision or a painful, red or cold limb
  - Signs of infection
  - Unexpected bruising or bleeding
  - Feeling very tired or breathless
  - Swollen legs
  - Palpitations or a racing heart
  - Severe tummy or back pain
  - Tell your haematology team if you get any other side effects. They may be able to suggest things to help.

**Do not stop taking ponatinib without discussing it with your haematology team.**

[Download our leaflet about ponatinib](#) 

<https://lcdemo-stage.gb.aldryn.io/about-leukaemia/treatments/ponatinib/>

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## About ponatinib

Ponatinib is a type of medicine called a tyrosine kinase inhibitor (TKI). It blocks an abnormal protein called BCR-ABL, which is a type of tyrosine kinase. This abnormal protein is present in people with CML. It encourages the blood-forming cells in your bone marrow to make too many white blood cells. Blocking the protein helps stop the leukaemia cells from multiplying.

The brand name of ponatinib is Iclusig.

Ponatinib is used as a second-line or later-line treatment for CML. Your haematology team might recommend it for you if you have CML and:

- You have a genetic change in your leukaemia cells called a *T315I* mutation. This can make CML resistant to some other TKIs.
- You've had previous treatment with dasatinib or nilotinib (and potentially other TKIs) but it either:
  - Did not work
  - Stopped working
  - Caused side effects that were difficult to cope with, and imatinib is not suitable for you

Ponatinib is also licensed to treat adults with some types of [acute lymphoblastic leukaemia](#) (ALL). It is not licensed to treat children.

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## Before taking ponatinib

Before starting your course of ponatinib, your haematology team will carry out checks to make sure it's suitable for you. These include:

- Checks of your heart health, like taking your pulse and blood pressure, and an electrocardiogram (ECG). Ponatinib may not be suitable if you have heart problems.
- Blood tests to check the level of cholesterol and sugars in your blood.
- Blood tests to check how well your liver is working.

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- Blood tests to check for viruses like hepatitis B. Ponatinib can reactivate a previous hepatitis B infection, so if you have it you may need to take an antiviral treatment to prevent this.

They will also check to see if you have any medical conditions such as diabetes, lung conditions or liver problems.

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## How to take ponatinib

Ponatinib comes as a film-coated tablets containing 15mg, 30mg or 45mg of ponatinib. The number of the tablets you need to take depends on your dose and the strength of the tablets. This should be printed on the named label on the medicine packaging. If you are not sure, ask your doctor or nurse.

- You should take ponatinib once a day with a glass of water. You can take it with or without food.
- Do not take ponatinib with grapefruit or grapefruit juice because this affects how much of it your body absorbs.
- Try to take your dose at around the same time every day if you can.
- Swallow the tablets whole. Do not crush or dissolve them.
- If you forget to take ponatinib, skip your missed dose and then take your next dose as usual. It is important not to take a double dose.

## Dose

The standard starting dose of ponatinib for adults is 45mg once daily. But it is common for your haematology team to suggest a different dose, depending on your circumstances. They will tell you what dose they recommend for you, and may reduce your dose over time.

- People over 65 can usually take the same dose as other people with CML.
- If you have liver or kidney problems, you usually start on the same dose as other people. But your haematology team might monitor you more closely.

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## Precautions

Some medicines or drugs may interact with ponatinib. It is important to tell your haematology team about any medicines or supplements you are taking. This includes prescribed medicines and medicines you have bought yourself without a prescription.

Examples include:

- Some medicines used to treat infections
- Some medicines used to lower your cholesterol level
- Some medicines used to prevent blood clots
- Some medicines used to treat epilepsy
- Some medicines used to treat depression
- Methotrexate, a medicine used to dampen your immune system
- Colchicine, a medicine used to treat gout
- Digoxin, a medicine used to treat heart failure or abnormal heart rhythms
- Herbal medicines such as St John's Wort
- Grapefruit or grapefruit juice

Ponatinib may cause dizziness, tiredness or blurred vision. Take care if you are driving or using tools or machinery.

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## Pregnancy and breastfeeding

Ponatinib may harm unborn babies.

- If you could get pregnant, or make someone pregnant, it's important to use effective contraception while you are taking ponatinib.
- If you're taking ponatinib and you think you might be pregnant, tell your haematology team as soon as possible. They will talk to you about your treatment options. They may recommend stopping treatment for a while or switching to a different treatment.
- If you are planning to get pregnant in the future, tell your haematology team. They will talk to you about your treatment options.

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## Breastfeeding

Scientists are not sure if ponatinib passes into breastmilk. If it does, it could be dangerous for breastfed babies or children. You should not breastfeed while you are taking ponatinib.

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## Monitoring

During your treatment with ponatinib, you will have regular tests to check how well your CML is responding to treatment. These will usually be blood tests and sometimes bone marrow tests. You will probably have blood tests every few weeks at first. If you do not have any problems, they will become less frequent.

### Monitoring your response to treatment

Tests to monitor how well your CML is responding to ponatinib look at:

- Your blood cell counts.
- The level of the BCR-ABL1 fusion gene in your white blood cells. This is called 'molecular response'.

Your haematology team will use the results of these tests to check how well ponatinib is working for you.

### What your molecular response means

Molecular response is the most sensitive and accurate measure of response. It is measured using a blood test called PCR.

There are different levels of molecular response (MR):

- MR1: Less than 1 in 10 white blood cells (10%) has the *BCR-ABL1* fusion gene. If ponatinib is working well, you should reach MR1 within 3 months of starting treatment.
- MR2: Less than 1 in 100 white blood cells (1%) has the *BCR-ABL1* fusion gene. If ponatinib is working well, you should reach MR2 within 6 months of starting treatment.
- MR3: Less than 1 in 1,000 white blood cells (0.1%) has the *BCR-ABL1* fusion gene. This is sometimes called a **major molecular response** (MMR). If ponatinib is working well, you should reach MR3 within 12 months of starting treatment.

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- MR4: Less than 1 in 10,000 white blood cells (0.01%) has the *BCR-ABL1* fusion gene. This is sometimes called a **deep molecular response** (DMR).
- MR5: Less than 1 in 100,000 white blood cells (0.001%) has the *BCR-ABL1* fusion gene. This is also called a **deep molecular response** (DMR).
- Levels below MR5 cannot usually be detected. This is called a **complete molecular response**.

If your *BCR-ABL1* levels have dropped, but you haven't quite met the required targets, you may be in a 'warning' category. You should discuss your options with your haematologist.

Your molecular response can be used to detect any difficulties in treatment early on. It is an essential part of safe monitoring.

## Monitoring your body's response to ponatinib

Your haematology team will also check how well your body is coping with ponatinib treatment. This might include:

- Blood tests to check how well your liver, pancreas and bone marrow are working. If these show problems, you might need to stop ponatinib for a while or take a lower dose.
- Blood pressure checks. Ponatinib may increase your blood pressure. If this happens, your doctor might prescribe blood pressure medications. If your blood pressure is very high, you may need to stop taking ponatinib for a while.
- Blood tests to check your blood sugar and cholesterol levels.

## Long term follow-up

Once you have reached a response to treatment, your haematology team will make a follow-up care plan for you. You will have regular follow-up appointments to check for any complications or signs you may have lost your response to treatment.

"I accept I'll be having blood tests and taking medication for the rest of my life but while this disease is part of my life and always will be, I won't let it define me."

— *Marisa, diagnosed with CML at 18*

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It is important to go to your follow-up appointments. This is so your team can check how well your treatment is working and how your body is coping. You are likely to have blood tests every few months, and possibly a bone marrow test if you lose response.

Your follow-up appointments will continue in the long term. How often you have appointments will depend on your individual needs - for example, any support you need to manage ongoing side effects.

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## How long to take ponatinib

Most people carry on taking ponatinib for as long as it works. Your haematology team may suggest stopping your ponatinib treatment and trying a different treatment if:

- It is not working well
- It stops working
- You are having side effects that are difficult to cope with

They are unlikely to suggest stopping CML treatment completely, because most people who take ponatinib would not be suitable for treatment-free remission.

Your haematology team might discuss reducing your ponatinib dose.

## Reducing your ponatinib dose

Your haematology team might suggest reducing your dose of ponatinib if:

- You have responded well to treatment
- You are getting difficult side effects
- They want to reduce your chance of getting serious complications from ponatinib treatment

They will monitor your treatment response closely after reducing your dose. If you lose your response, they might slowly increase the dose until you reach a response again. The aim is to find the lowest dose that works for you. This keeps your risk of side effects and complications as low as possible.

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## Side effects

You may get some side effects while you are taking ponatinib. They are usually mild to moderate. Some people have very few side effects, whereas other people experience more serious side effects.

The possible side effects of ponatinib are very similar to those with other TKIs. Some are more common, and some less common. Most people with CML need to take one of the TKIs. Your haematology team should tell you about the likelihood of key side effects with different medications.

If you are getting side effects that are difficult to cope with, your haematology team might suggest reducing your dose of ponatinib. They may then try slowly increasing it to find a dose that works for you.

**Tell your haematology team if you get any side effects. They may be able to adjust your dose of ponatinib, prescribe medicines to help, or suggest things to help you cope.**

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## Serious side effects

**The following side effects may be serious and require treatment. Contact your doctor straight away if you have any of these side effects.**

Ponatinib can cause blocked blood vessels, which can be serious. Your haematology team will check your heart health and keep you on the lowest effective dose of ponatinib to keep the risk as low as possible. But up to 1 in every 10 people taking ponatinib may get a blocked blood vessel, although this is lower on smaller doses.

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Blocked blood vessels are not always serious, but they can be. Contact your doctor straight away if you get any of the following:

### **Symptoms of angina or a heart attack**

These include:

- Pain or discomfort in your chest, back, arm or shoulder
- Shortness of breath
- Feeling sick
- Sweating and light-headedness

### **Symptoms of a stroke or mini-stroke**

These can include:

- Drooping of your face on one side
- Not being able to lift both arms and keep them there
- Slurred or garbled speech
- Not being able to understand what is being said to you

### **Blurred vision or loss of vision**

This could be due to a blocked blood vessel in your eye

### **A painful, red or cold limb**

This could be due to a blood clot or blocked blood vessel

Other side effects of ponatinib that can be serious include:

- Severe tummy or back pain, which could be due to inflammation in your pancreas
- Changes in your heart rhythm, like palpitations or a racing heart
- Unexpected bruising or bleeding. Your levels of platelets may be low. Your haematology team may stop ponatinib and give you blood transfusions. Signs of bleeding can include:
  - Nosebleeds
  - Bleeding gums
  - Blood spots or rashes
  - Blood in your wee, poo or vomit, or black poo
- Infections. This may be due to a low white blood cell count, which means you can't fight infections as well as usual. If you get an infection, you need prompt

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treatment and you may need to stop ponatinib treatment for a while. Signs of infection include:

- High temperature over 37.5°C or severe chills
  - Sore throat
  - Cough
  - Pain when you wee or weeing more often than usual
  - Diarrhoea
  - A red, hot, swollen patch of skin
- Feeling very tired or short of breath – your level of red blood cells may be low
  - Difficulty breathing, which could be due to a lung infection, a blood clot or fluid on your lungs
  - Heart failure, which can cause fatigue, breathlessness or swollen legs

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## Very common side effects

Very common side effects affect more than 10 in every 100 people who are taking ponatinib.

Very common side effects include:

- Infections in your nose and throat
- Decreased appetite
- Difficulty sleeping
- Headache
- Dizziness
- High blood pressure
- Shortness of breath
- Cough
- Diarrhoea or constipation
- Feeling sick or being sick
- Tummy pain
- Changes in your liver function (this shows on blood tests)
- Rash, dry skin and itching
- Bone, joint and muscle pain
- Tiredness and lack of energy

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- Swollen tissues due to build-up of fluid
- High temperature

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## Common side effects

Common side effects affect more than 1 but less than 10 out of every 100 people who are taking ponatinib.

Common side effects include:

- Lack of energy
- Migraine
- Chills or flu-like symptoms
- Dehydration, which can make you feel thirsty, dizzy and faint
- Dry, sore, red, watery eyes and blurred vision
- Swelling in your face or around your eyes
- Dry mouth or sores or cracks at the corner of your mouth
- Nose bleeds
- A change in your voice
- Indigestion
- Bloating
- Tummy pain
- Bleeding in your stomach
- Weight loss
- Skin rashes or dry, itchy or flaky skin that may be red, purple or darker than your usual skin tone
- Swollen ankles due to water retention
- Hair loss
- Hot flushes
- Night sweats and excessive sweating
- Changes in your sense of touch, like numbness or pins and needles
- Difficulty getting or keeping an erection
- Low thyroid function, which can cause tiredness, sensitivity to cold, constipation and weight gain
- An imbalance in mineral levels in your blood (this shows on blood tests)

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This is not a full list of all the side effects that can happen. The [patient information leaflet](#) has more information.

**If you are worried about any side effects or symptoms you have, contact your haematology team.**

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## If ponatinib does not work

If ponatinib hasn't worked, or has stopped working for you, there are other options. These could include:

- A different TKI. All TKIs work in slightly different ways. If your CML does not respond to ponatinib, it might still respond to a different TKI. Some people try several different TKIs.
- A stem cell transplant using donor cells. This is called an allogeneic stem cell transplant.

Your haematology team will tell you which option they recommend for you.

We have separate information about:

- [Second- and later-line treatments for CML](#)
- [Stem cell transplants](#)

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## Need support?

You are not alone. We're here for you whether you have a diagnosis yourself or know someone who has. If you'd like advice, support, or a listening ear, call our freephone helpline on 08088 010 444 or send a WhatsApp message to 07500 068 065.

[Helpline and WhatsApp →](#)

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## Help us improve our information

We aim to provide information that's reliable, up-to-date, and covers what matters to you. Please complete our short survey to help us improve our information and make sure it meets your needs.

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### About our information

This information is aimed at people in the UK. We do our best to make sure it is accurate and up to date but it should not replace advice from your health professional. Find out more [about our information](#).

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