Asciminib

Asciminib is a targeted treatment used for some people with chronic myeloid leukaemia (CML) if other treatments have not been suitable

Summary

- Asciminib 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 asciminib.
- Your haematology team will also carry out tests to check how your body is coping with asciminib treatment.
- Side effects of asciminib 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:
    - Unexpected bruising or bleeding
    - Infections
    - Feeling very tired or short of breath
    - Severe tummy pain
    - High blood pressure
    - Palpitations or an irregular heart beat
- Tell your haematology team if you get any other side effects. They may be able to suggest things to help.

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

Download our leaflet about asciminib

About asciminib

Asciminib 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.

Asciminib blocks a very specific part of the BCR-ABL protein, so it works in a slightly different way from other TKIs.

The brand name of asciminib is Scemblix.

Asciminib is suitable for adults with chronic phase CML. Your haematology team might recommend it for you if:

- You've already had treatment with at least two other TKIs
- Previous treatment either did not work, stopped working, or caused side effects that were difficult to cope with
- You do not have a genetic change in your leukaemia cells called a T315I mutation, which can make CML resistant to some TKIs

> "I was placed on 400mg of imatinib, but it caused me bone pain, so after a couple of months with no improvement I was switched to 100mg of dasatinib which I stayed on for about 12 years. Ultimately, dasatinib caused me a lot of fatigue so I have recently started on asciminib. As CML patients we are very fortunate to have many treatment options available to us."
>
> — *David, diagnosed with CML*

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Before taking asciminib

Before starting your course of asciminib, 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). Asciminib may not be suitable if you have heart problems.
- Blood tests to check the level of fats in your blood.
- Blood tests to check for viruses like hepatitis B. Asciminib 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 liver or pancreas problems.

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How to take asciminib

Asciminib comes as film-coated tablets containing 20mg or 40mg of asciminib. The number of tablets you need to take depends on your dose and the strength of the film-coated tablets. This should be printed on the named label on the medicine packaging. If you are not sure, ask your doctor or nurse.

- You take asciminib once or twice a day. Your doctor or nurse will tell you which they recommend for you. Try to take it at the same time each day if you can.
- Swallow the asciminib tablets whole with a glass of water. Do not split, crush or chew them.
- Do not take asciminib with food because this could affect how much of it your body absorbs.
    - Wait at least 2 hours after eating **before** taking asciminib.
    - Do not eat for at least 1 hour **after** taking asciminib.

If you forget to take asciminib:

- **If you usually take it once a day** and you miss a dose by less than 12 hours, take it when you remember. If you miss it by more than 12 hours, skip the missed dose and just take your usual dose the next day.
- **If you usually take it twice a day** and you miss a dose by less than 6 hours, take it when you remember. If you miss it by more than 6 hours, skip the missed dose and just take your next dose at the usual time.

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Dose

Most adults with CML take 80mg asciminib every day. Your haematology team may suggest a different dose, depending on your circumstances. They will tell you what dose they recommend for you.

People over 65 and people with liver or kidney problems can usually take the same dose as younger people.

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Precautions

Some medicines or drugs may interact with asciminib. 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 epilepsy
- Some pain killers or sedatives you might have if you have an operation
- Some medicines used to treat migraine or dementia
- Medicines that may have a side effect of changing your heart rhythm
- Herbal medicines such as St John's Wort
- Some medicines to prevent blood clots, like warfarin

Asciminib may cause blurred vision. Take care if you are driving or using tools or machinery.

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Pregnancy and breastfeeding

Asciminib may harm unborn babies.

- If you could get pregnant, or make someone pregnant, it's important to use effective contraception while you are taking asciminib and for 3 days after stopping treatment.
- If you're taking asciminib and you think you might be pregnant, tell your haematology team as soon as possible. They will talk to you about your 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.

Breastfeeding

Scientists are not sure if asciminib passes into breastmilk. If it does, it could be dangerous for breastfed babies or children. You should not breastfeed while you are taking asciminib and for at least 3 days after you stop.

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Monitoring

During your treatment with asciminib, your haematology team will carry out 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

To monitor how well your CML is responding to asciminib, your haematology team will carry out the following tests:

- 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 asciminib 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 asciminib 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 asciminib 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 asciminib is working well, you should reach MR3 within 12 months of starting treatment.
- 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). If you reach and maintain a DMR, you might eventually be able to stop treatment.
- 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). If you reach and maintain a deep molecular response, you might eventually be able to stop treatment.
- 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 if you can stop treatment.

Monitoring your body's response to asciminib

Your haematology team will also check how well your body is coping with asciminib treatment using the following tests:

- Blood tests to check how well your kidneys, pancreas and bone marrow are working.
- Blood pressure checks. Asciminib can 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 asciminib for a while.
- ECG checks and blood tests to check your heart health.

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.

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.

> "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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How long to take asciminib

You usually carry on taking asciminib for as long as it works. Your haematology team may suggest stopping your asciminib 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

Your haematology team might also discuss reducing your dose, or stopping treatment completely.

Reducing your asciminib dose

Your haematology team might suggest reducing your dose of asciminib if you are getting difficult side effects or you are in a major molecular response.

Your haematology team 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 as low as possible.

Stopping asciminib

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

Asciminib has only been available in the UK since 2022 so there is very little experience of stopping it to see if CML stays under control without medicines. This is called treatment-free remission. In theory, asciminib may be similar to other TKIs in terms of stopping treatment. So your haematology team might discuss the possibility of treatment-free remission in the future, if it may be suitable for you.

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Side effects

You may get some side effects while you are taking asciminib. For most people, these are usually mild to moderate. They may differ from day to day. Some people have very few side effects, whereas other people experience more serious side effects.

The possible side effects of asciminib 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 asciminib. 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 asciminib, 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.

- Unexpected bruising or bleeding. Your levels of platelets may be low. Your haematology team may stop asciminib 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 will need prompt treatment and you may need to stop asciminib 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
- Feeling very tired or short of breath due to low red blood cells (anaemia).
- Inflammation of your pancreas (pancreatitis). You will have regular blood tests to check the levels of your pancreatic enzymes. If they are high, your haematology team might recommend pausing asciminib for a while, or stopping completely. Symptoms of pancreatitis include:
    - Severe pain in your upper tummy that may spread to your back
    - High temperature (over 37.5°C)
    - Fast heart rate
    - Being sick

- High blood pressure. Your haematology team will check your blood pressure regularly. If it's high, you might need blood pressure medicine. If it's very high, you might need to pause or stop asciminib. High blood pressure does not usually cause any symptoms, but if it is very high, you might get:
    - Headache
    - Dizziness
    - Shortness of breath
    - Chest pain
- Palpitations or an irregular heart beat.
- Any other unusual or worrying symptom.

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Very common side effects

This is not a full list of all the side effects that can happen. The patient information leaflet in your medicine package has more information. Or you can find the leaflet by searching for 'asciminib' at the Electronic Medicines Compendium.

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

- Infections in your nose and throat
- Headache
- Dizziness
- Cough
- Feeling sick or being sick
- Diarrhoea
- Tummy pain
- Rash
- Difficulty sleeping
- Shortness of breath
- Muscle, bone and joint pain

- Fatigue
- Itching
- Changes in fat levels in your blood (this will show on blood tests)
- Changes in the levels of your liver enzymes (this will show on blood tests)

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Common side effects

This is not a full list of all the side effects that can happen. The patient information leaflet in your medicine package has more information. Or you can find the leaflet by searching for 'asciminib' at the Electronic Medicines Compendium.

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

- Lung or airway infections
- Flu
- Decreased appetite
- Dry eyes or blurred vision
- Shortness of breath
- Chest pain
- Abnormal heart rhythm
- Hives
- High temperature
- Swelling due to water retention, especially in places like your ankles

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

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If asciminib does not work

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

- A different TKI. All TKIs work in slightly different ways. If your CML does not respond to asciminib, it might still respond to a different one. 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.

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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 →

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.

Complete our short survey →

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