Bosutinib

Bosutinib is a targeted treatment used for some people with chronic myeloid leukaemia (CML) if other treatments are not suitable.

Summary

- Bosutinib is a type of medicine called a tyrosine kinase inhibitor (TKI).
- It comes as film-coated tablets 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 bosutinib.
- Your haematology team will also carry out tests to check how your body is coping with bosutinib treatment.
- Side effects of bosutinib 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:
    - Diarrhoea, feeling sick or being sick
    - Unexpected bruising or bleeding
    - Infections
    - Fainting, palpitations or an irregular heart beat
    - A painful, blistering rash
    - Yellow eyes, itching, dark-coloured wee or tummy pain under your ribs on the right side
    - Breathlessness, cough or swollen feet, ankles or legs
    - Sickness, tummy pain, muscle cramps, weeing less than usual, blood in your wee or fits
- Tell your haematology team if you get any other side effects. They may be able to suggest things to help.

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

Download our leaflet about bosutinib

About bosutinib

Bosutinib 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 for bosutinib is Bosulif.

Bosutinib is a common second-line or later-line treatment for CML. It is suitable for adults with CML. Your haematology team might recommend it for you if you have CML and:

- You've already had treatment with at least one other TKI
- Previous treatment either did not work, stopped working, or caused side effects that were difficult to cope with
- Imatinib, dasatinib or nilotinib are not suitable for you (or you've already had them)

Bosutinib is also licensed for adults with newly-diagnosed chronic phase CML, but it is not available on the NHS for this.

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Before taking bosutinib

Before starting your course of bosutinib, 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). Bosutinib can cause changes to your heart rhythm so it may not be suitable if you have heart problems.
- Blood tests to check how well your liver is working. Bosutinib can affect your liver function so it may not be suitable for you if you already have problems with your liver.
- Blood tests to check if you have, or have had, virus infections like hepatitis B. Bosutinib can reactivate hepatitis B infection, so if you have it you may need to take an antiviral treatment to prevent this.
- Blood tests to check the level of fats and sugars in your blood.

They will also check to see if you have any medical conditions such as diabetes, lung conditions, infections or fluid retention.

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How to take bosutinib

Bosutinib comes as a film-coated tablet containing 100mg, 400mg or 500mg of bosutinib. The number of tablets you need to take depends on the 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 bosutinib once a day with food. Try to take it at the same time every day if you can.
- Do not take bosutinib with grapefruit or grapefruit juice because this increases how much of it your body absorbs. This could cause more side effects.

> **If you forget to take bosutinib:**
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> - **If 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.**

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Dose

Most people with CML take 400mg or 500mg bosutinib daily. Your haematology team may suggest a higher or lower dose, depending on your circumstances. They will tell you what dose they recommend for you.

- People over 65 can usually take the same dose as other people with CML.
- People with kidney problems usually start on a lower dose. Your haematology team might increase it if needed as long as you have not had any concerning side effects.

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Precautions

Some medicines may interact with bosutinib. 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:

- Medicines used to treat abnormal heart rhythms
- Medicines that may have a side effect of changing your heart rhythm
- Some medicines used to treat infections
- Some medicines used to treat high blood pressure
- Some antacids and other medicines that reduce stomach acid, such as omeprazole
- Some medicines used to treat epilepsy
- Some medicines used to treat sickness or vomiting
- Some medicines used to treat depression, schizophrenia or sleep disorders
- Some medicines used to treat lung cancer
- Herbal medicines such as St John's Wort
- Grapefruit or grapefruit juice

Tell your haematology team if you start any new medicines or supplements when you are taking bosutinib.

Bosutinib can make your skin more sensitive to the sun. It is important to use sunscreen with a high sun protection factor (factor 50) on exposed areas.

Bosutinib may make you feel dizzy or cause blurred vision. Take care if you are driving or using tools or machinery.

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Pregnancy and breastfeeding

Bosutinib may harm unborn babies.

- If you could get pregnant, it's important to use effective contraception while you are taking bosutinib and for at least 1 month afterwards.
    - If you get diarrhoea or vomiting during bosutinib treatment, oral contraceptives may be less effective than usual and you may need to take extra precautions.
- If you're taking bosutinib 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 or make someone pregnant in the future, tell your haematology team. They will talk to you about your treatment options. They may refer you to a specialist to talk about ways to preserve your fertility.

Breastfeeding

Scientists are not sure if bosutinib passes into breastmilk. If it does, it could be a risk for breastfed babies or children.

> **You should not breastfeed while you are taking bosutinib.**

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Monitoring

During your treatment with bosutinib, you will have regular tests to check how well your CML is responding and how your body is coping with 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 bosutinib 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 bosutinib 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 bosutinib 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 bosutinib 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 bosutinib 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 bosutinib

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

- Blood tests to check how well your liver, kidneys, pancreas and bone marrow are working.
    - If your blood tests show problems with your liver function or bone marrow, you may need to stop taking bosutinib for a while, try a lower dose, or stop taking it completely.
- Blood pressure checks. Bosutinib 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 bosutinib for a while.
- ECG checks and blood tests to check your heart health.
- Blood tests to check your blood sugar and fat 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.

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 bosutinib

Most people carry on taking bosutinib for as long as it is working. Your haematology team may suggest stopping bosutinib 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 bosutinib dose

Your haematology team might suggest reducing your dose of bosutinib 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 bosutinib

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

There is less experience of stopping bosutinib than some of the other CML medicines. But your haematology team might discuss stopping it if:

- You started taking bosutinib because your previous treatment caused side effects that were difficult to cope with (not because it did not work well) **AND**
- You have been taking CML treatment for at least 3 years (ideally 5 years) **AND**
- Your CML has been in deep molecular response (MR4 or MR5) for at least 2 years

This is called treatment-free remission. Your haematology team will talk to you about the benefits and risks of treatment-free remission, so you can decide if it's something you would like to try.

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Side effects of bosutinib

You may get some side effects while you are taking bosutinib. For most people, these side effects 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 bosutinib 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 bosutinib. 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 bosutinib, prescribe medicines to help, or suggest things to help you cope.**

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Serious side effects of bosutinib

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

- Diarrhoea, feeling sick (nausea) or being sick (vomiting). If you need it, your doctor might prescribe anti-diarrhoeal medicines, anti-sickness medicines or fluids (for example, oral rehydration solution). They may stop bosutinib temporarily, reduce your dose, or stop bosutinib completely.
- Unexpected bruising or bleeding. Your levels of platelets may be low. Your haematology team may stop bosutinib 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 treatment and you may need to stop bosutinib 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
- Fainting, palpitations or an irregular heart beat. You may have developed an abnormal heart rhythm. The checks you have before and during bosutinib treatment reduce the risk of this, but it can still happen.
- A painful, blistering rash that may spread to your mouth and lips. If you get a severe skin reaction like this, you may need to stop taking bosutinib completely.
- Yellow eyes, itching all over, dark-coloured wee or tummy pain under your ribs on the right side. These could be signs of liver problems. Your doctor might

recommend stopping bosutinib for a while, trying a lower dose, or stopping it completely.

- Breathlessness, cough or swollen feet, ankles or legs. This is because bosutinib can cause water to build up in your body or lungs. Medicines called diuretics can help treat water retention.
- Sickness, tummy pain, muscle cramps, weeing less than usual, blood in your wee or fits (seizures). These could be symptoms of a condition called tumour lysis syndrome. It affects less than 1 in every 100 people who take bosutinib, but it can happen if bosutinib makes your cancer cells break down too quickly. This leads to a build up of chemicals in your bloodstream. It needs urgent treatment. Your haematology team will make sure you are not dehydrated before you start treatment, to reduce the risk of this happening.
- 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 bosutinib.

Other very common side effects include:

- Feeling sick or being sick
- Constipation
- Tummy pain
- Feeling very tired or short of breath due to low red blood cells (anaemia)
- Breathlessness or cough due to fluid around the lungs
- Skin rash, which may be itchy
- Sore throat, runny nose and chest or airway infections

- Headache
- Decreased appetite
- Dizziness or weakness
- Joint or back pain
- High temperature
- Fatigue
- Swollen hands, feet or face

It is very common to get diarrhoea when you first start taking bosutinib. This usually happens within a few days of starting or increasing your dose, but it can happen at any time. The symptoms usually get better after a week or two as your body gets used to the medicine.

It is important to tell your haematology team about your symptoms. They might prescribe anti-diarrhoeal medication to help, or they might consider starting you on a lower dose of bosutinib at first. They may recommend pausing or stopping bosutinib if your diarrhoea is particularly bad, but this is not usually needed.

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

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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 bosutinib.

Common side effects include:

- High blood pressure
- Tummy pain due to inflammation of your pancreas or stomach
- Raised, itchy, red bumps on your skin (hives)
- Muscle pain
- Chest discomfort or pain
- Sensitivity to the sun
- Spots
- Dehydration, which could cause thirst, dizziness, fainting, rapid breathing and a racing heart
- Change in taste
- Ringing in the ears
- Bleeding in your gut
- Imbalance of mineral levels in your blood
- Build up of fluid around the heart
- Liver problems
- Kidney problems

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

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If bosutinib does not work

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

- Increasing your dose of bosutinib.

- A different TKI. All TKIs work in slightly different ways. If your CML does not respond to bosutinib, 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 →

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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