

Dasatinib for chronic myeloid leukaemia (CML)

Chronic myeloid leukaemia (CML) is a type of blood cancer that involves the white blood cells. It develops slowly over many years. The most common treatment is a type of targeted therapy called a tyrosine kinase inhibitor (TKI). This booklet is about dasatinib, a TKI that is a common treatment for CML. We cover what it is, who might have it and how to take it. We also cover its main side effects and any special precautions you need to take while you're on it.

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Throughout this leaflet, you will see URLs that link to webpages for further support. If you are not able to access the webpages, please email information@leukaemiacare.org.uk.

Summary

- Dasatinib is a type of medicine called a tyrosine kinase inhibitor (TKI).
- It comes as film-coated tablets that you take every day. 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 dasatinib.
- Your haematology team will also carry out tests to check how your body is coping with dasatinib treatment.
- Side effects of dasatinib 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:
 - Rapid weight gain
 - Signs of infection
 - Unexpected bruising or bleeding
 - Shortness of breath or chest 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 dasatinib without discussing it with your haematology team.

About dasatinib

Dasatinib is a type of medicine called a tyrosine kinase inhibitor (TKI). It blocks an abnormal protein called BCR-ABL1, 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.

There are several different brands of dasatinib, but they all contain the same active medicine. Brand names include:

- Dasatinib Sandoz
- Dasatinib Zentiva
- Sprycel

Dasatinib is a common treatment for CML suitable for adults and children. Your haematology team might recommend it for you if:

- You have just been diagnosed with CML
- You have chronic or accelerated phase CML and previous treatment, including imatinib, either:
 - Did not work
 - Stopped working
 - Caused side effects that were difficult to cope with

Before taking dasatinib

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

- Checks of your heart health, like taking pulse and blood pressure measurements, and an electrocardiogram (ECG). Dasatinib may not be suitable if you have heart problems.
- Blood tests to measure the level of fats and sugars in your blood.
- Blood tests to check for viruses like HIV or hepatitis B. Dasatinib can reactivate 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 diseases or liver problems.

How to take dasatinib

Dasatinib comes as film-coated tablets in a number of different strengths. The number of 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 dasatinib every day as prescribed so it can work as well as possible. Try and take it at the same time every day if you can.
- Swallow your dasatinib tablets whole with a large glass of water. You can take it with or without food.
- Do not take dasatinib with grapefruit or grapefruit juice because this affects how much of it your body absorbs.
- Do not cut, crush, chew or dissolve the tablets because this can alter the dose you absorb into your body.
- If you forget to take your dasatinib tablet, skip the missed tablet and take your next dose at the normal time. It is important not to take a double dose.

Dasatinib also comes as a powder that can be dissolved in water. This is usually used for children. It is also an option for adults who cannot swallow tablets.

Dose

Most adults with CML start on 100mg dasatinib daily in the chronic phase or 140mg daily in the blast phase. Your haematology team might increase or decrease your dose depending on your circumstances. They may start you on a lower dose if they are worried about side effects. They will tell you what dose they recommend for you.

- People over 65 and those with liver or kidney problems can usually have the same starting dose as other people.
- Doses for children are based on their body weight.

You take dasatinib once a day.

"My treatment was one pill a day, I didn't have to go through IV chemo, I wasn't likely to lose my hair and the side effects from my medication were minimal. Most days I felt normal."

Jo, diagnosed with CML at 34

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

Precautions when you are taking dasatinib

There are several precautions to be aware of when you are taking dasatinib.

- Some medicines may interact with dasatinib. 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 treat epilepsy
 - Antacids and other medicines that reduce stomach acid, such as omeprazole
 - Herbal medicines such as St John's Wort
 - Medicines to prevent blood clots, like aspirin or warfarin
 - Grapefruit or grapefruit juice
- Dasatinib may make you feel dizzy or drowsy or cause blurred vision. Take care if you are driving or using tools or machinery.

Pregnancy and breastfeeding

Dasatinib may harm unborn babies.

- If you could get pregnant or make someone pregnant, it is important to use effective contraception while you are taking dasatinib.
- If you are taking dasatinib 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.

Scientists think dasatinib probably passes into breastmilk, which could be a risk to breastfed babies or children. You should not breastfeed while you are taking dasatinib.

Monitoring during dasatinib treatment

During your treatment with dasatinib, 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 are likely to have blood tests every week or two for the first few months of treatment. If you respond well and your body is coping with the treatment, this might reduce to every 3 months.

Monitoring your response to treatment

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

- Your blood cell counts.
- The level of the *BCR-ABL1* fusion gene in your white blood cells. This is called 'molecular response' ([page 7](#)).

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

Monitoring your body's response to dasatinib

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

- Blood tests to check your blood counts. Dasatinib can cause low red blood cell counts, white blood cell counts and platelet counts. Your haematology team will monitor this carefully. They may reduce your dose, or stop dasatinib for a while until your blood counts improve.
- Blood tests to check how well your liver, kidneys, pancreas and thyroid are working.
- Blood pressure checks. Dasatinib 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 dasatinib for a while.
- ECG checks and blood tests to check your heart health.
- Blood tests to check your blood sugar and fat.

How long to take dasatinib

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

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 dasatinib 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 dasatinib 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 dasatinib 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 DMR, 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.

Reducing your dasatinib dose

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

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 as low as possible.

Stopping dasatinib

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

Your haematology team might discuss stopping dasatinib completely if:

- You have been taking it for at least 3 years (ideally 5 years) **AND**
- Your CML has been in DMR (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.

We have [separate information about treatment-free remission](#). Follow the link or search 'treatment-free remission' at leukaemiacare.org.uk to download it or order a free copy.

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 signs of relapse or complications.

"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

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.

Side effects of dasatinib

You may get some side effects while you are taking dasatinib. 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 dasatinib 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.

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

Serious side effects of dasatinib

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 dasatinib 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 cannot fight infections as well as usual. If you get an infection, you need prompt treatment and you may need to stop dasatinib 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 – your level of red blood cells may be low.

- Chest pain, difficulty breathing or sweating a lot – you may have developed a heart problem. Your doctor will assess you. They may stop dasatinib treatment.
- Rapid weight gain or swelling in most of your body. This is because dasatinib can cause your body to retain water. Medicines called diuretics can help treat water retention.
- Shortness of breath or cough - you may have fluid on your lungs. You may have a chest X-ray and maybe a short course of steroids. Your dasatinib might need to be stopped, or your dose reduced.
- Fainting or seizures (fits), which could be due to an abnormal heart rhythm.
- Any other unusual or worrying symptom.

Common side effects of dasatinib

You may experience some of the following common side effects when taking dasatinib. Most people only experience some mild to moderate side effects.

Tell your haematology team if you get any side effects. They may be able to suggest things to help.

"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

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

Very common side effects

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

Very common side effects include:

- Infections
- Headache
- Feeling tired or weak
- Bleeding
- Shortness of breath due to a build-up of fluid around your lungs
- Feeling sick or being sick



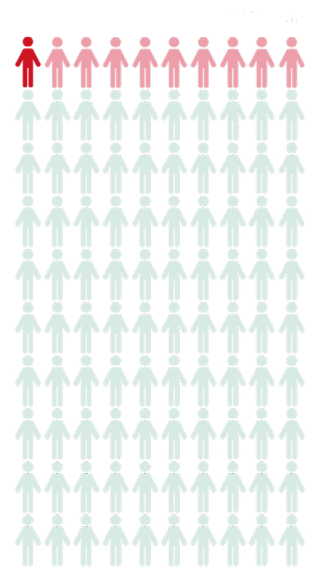
- Diarrhoea – if this affects you badly, your doctor might prescribe anti-diarrhoeal medicine
- Tummy pain
- Skin rash
- Muscle or bone pain
- Swelling in your face or limbs due to a build-up of fluid
- High temperature
- Low blood counts

Common side effects

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

Common side effects include:

- Change in appetite
- Depression
- Blurred vision or dry eyes
- Ringing in your ears
- Difficulty sleeping
- Feeling dizzy or drowsy
- Tingling, numbness or other changes in your sense of touch
- Changes in taste
- Heart problems, including palpitations, a change in your heart rhythm or a fast heart rate
- Cough, lung inflammation or fluid on your lungs
- Bleeding from your gut
- Inflammation of your mouth, stomach or large bowel
- Indigestion
- Bloating
- Constipation
- Hair loss
- Dry, red, itchy skin, hives or acne
- Excessive sweating
- Joint and muscle pain, weakness, spasms or stiffness



- Feeling generally weak
- Pain, including chest pain
- General swelling of your body due to fluid retention
- Chills
- Change in weight
- Bruising
- High level of uric acid in your blood

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. You can also find this online. Search for 'dasatinib' at www.medicines.org.uk and select the brand of medicine you are taking.

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

Treatment options if dasatinib does not work

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

- Increasing your dose of dasatinib.
- A different TKI. All TKIs work in slightly different ways. If your CML does not respond to dasatinib, 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.

We have separate information about:

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

Follow the links or search 'CML' at leukaemiacare.org.uk to download them or find out how to order a free copy.

Further information

We have [more information about CML](#), including booklets and factsheets to download. Follow the link or search 'CML' at leukaemiacare.org.uk.

We also have [booklets you can order in print free of charge](#). Follow the link or search 'CML' at shop.leukaemiacare.org.uk.

We are grateful to Guy Hannah, consultant haematologist, Nick Duncan, consultant haematology pharmacist, and Abir, Colin and Graham, patient reviewers, for reviewing this information.

If you have any feedback on this information, or you'd like a list of the references we used to develop it:

- Email information@leukaemiacare.org.uk
- Call **01905 755 977**
- Write to **Leukaemia Care, One Birch Court, Blackpole East, Worcester, WR3 8SG**

If you need support

[We're here for you if you need support](#). Follow the link or search 'support for you' at leukaemiacare.org.uk to find out how we can help you.

If you'd like to talk to someone who understands what you're going through:

- Call our freephone helpline on **08088 010 444**
- Message us through WhatsApp on **07500 068065**

