Gilteritinib

Gilteritinib can be used to treat some adults with acute myeloid leukaemia (AML) that has not responded to treatment or has come back after treatment.

Summary

- Gilteritinib is used to treat some people with acute myeloid leukaemia (AML).
- Gilteritinib is a medicine that blocks a protein to help stop cancer cells from growing and dividing.
- It comes as film-coated tablets. You usually take three tablets once a day.
- You will have regular blood tests and heart scans to check how well the treatment is working and how your body is coping with it.
- You may get some side effects while you are taking gilteritinib. Some people have very few side effects, whereas other people experience more serious side effects.
- Some side effects can be serious if not treated promptly. Contact your haematology team straight away if:
    - You have unexpected bruising or bleeding, like nosebleeds, bleeding gums, blood spots or rashes
    - You feel tired, dizzy or short of breath
    - You have a high temperature (37.5°C to 38°C or higher), feel shivery or generally unwell
    - You have liver or kidney problems
    - You have diarrhoea
    - You have high or low blood pressure
    - You have a fever, cough or chest pain
    - You feel faint or light-headed
    - You have swollen legs, feet, ankles and possibly arms and hands
    - You have a rash, or rapid weight gain
    - You have fits (seizures), headaches, problems with your eyes or nerves
    - You have headaches, feel confused, or have a change in your mental status

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Leukaemia Care Registered Charity Number 1183890. Scotland Registered Charity Number SC049802
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About gilteritinib

Gilteritinib is a targeted medicine that blocks some proteins cells need to grow and divide. This includes a protein called FLT3. The FLT3 protein is abnormal in around 1 in every 3 people with AML due to a change in the FLT3 gene. It encourages the blood-forming cells in your bone marrow to make too many white blood cells. Blocking FLT3 helps stop the leukaemia cells from growing and dividing.

The brand name for gilteritinib is Xospata.

Your haematology team might recommend gilteritinib for you if:

- Your leukaemia cells have a change in the FLT3 gene **AND**
- Your AML hasn't responded to treatment (refractory) **OR**
- Your AML has come back after remission (relapsed)

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Before taking gilteritinib

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

- Blood tests to measure your blood counts
- Blood tests to check your liver and kidney function
- Tests and scans to check your heart function
- A pregnancy test

Things to tell your haematology team

Before starting treatment, you should let your haematology team know if you:

- Have or ever had any problems with your heart
- Have or ever had low levels of potassium or magnesium in your blood
- Have severe tummy or back pain and are feeling or being sick – this could be a sign that your pancreas is inflamed
- Are or think you may be pregnant

Some medicines or drugs may interact with gilteritinib. 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:

- St John's wort, a herbal medical used to treat depression
- Some medicines used to treat epilepsy
- Some medicines used to treat heart problems
- Some medicines used to prevent blood clots
- Some medicines used to treat infections
- Some medicines used to treat high blood pressure
- Some medicines used to treat depression
- Some medicines used to treat certain types of diabetes

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Taking gilteritinib

Gilteritinib comes as film-coated tablets. Most people take three tablets once a day. Your dose should be printed on the named label on the medicine packaging. If you are not sure, ask your doctor or nurse.

- You should take gilteritinib as prescribed so it can work as well as possible. Try and take it at the same time of day if you can.
- Swallow the gilteritinib tablets whole with a full glass of water. To make sure you get the right dose, do not break, crush, dissolve or chew the tablet.
- You can take the tablets with food or in between meals, whichever is best for you.
- If you are sick after taking a tablet, do not take another dose on the same day. Instead, wait until the next day and take your dose as normal. It is important not to take a double dose.
- If you forget to take your gilteritinib tablets, take it as soon as you remember on the same day. If it is the next day, just take your usual dose at the usual time. **Do not take a double dose to make up for forgotten tablets.**

Dose

Most adults with AML start on three gilteritinib tablets each day (120mg). If you have not responded after 4 weeks, your doctor might increase your dose to five gilteritinib tablets each day (200mg).

Your haematology team may suggest a different dose, depending on your circumstances. They will tell you what dose they recommend for you.

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Precautions

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

- Gilteritinib may make you feel dizzy. Take care if you are driving or using tools or machinery.
- Gilteritinib can affect your heart. If you have a history of heart problems or have any side effects during treatment that affect your heart, tell your haematology team.
- Gilteritinib can affect your pancreas. If you have a history of pancreas problems, or have pain in your upper tummy and back, feel sick or are being sick, tell your haematology team.

Differentiation syndrome

Sometimes gilteritinib might cause a serious problem called differentiation syndrome. It happens to less than 4 in every 100 people taking gilteritinib. This means more than 96 in every 100 people taking gilteritinib do not get it.

Differentiation syndrome can happen if recovering white blood cells release too many immune chemicals, which can trigger a severe reaction. Signs and symptoms of this include:

- Fever
- Shortness of breath
- Cough, chest pain and difficulty breathing
- Feeling faint or light-headed
- Swollen legs, feet, ankles and sometimes arms and hands
- Low blood pressure
- Rapid weight gain
- Rash
- Kidney problems

Your haematology team will monitor you for signs of differentiation syndrome. If it happens, it can be treated with steroids. You will be given an alert card with symptoms to look out for and details of who to contact if you get any of them.

Posterior reversible encephalopathy syndrome

Sometimes gilteritinib can cause swelling of parts of your brain. This is known as posterior reversible encephalopathy syndrome (PRES). It happens to less than 1 in every 100 people taking gilteritinib. This means more than 99 in every 100 people taking gilteritinib do not get it.

PRES can cause signs and symptoms like:

- Fits (seizures)
- Headaches
- Confusion
- Problems with your eyes and nervous system
- High blood pressure
- A change in your mental status

> **If you have any of these signs or symptoms, tell your haematology team.**

They will need to do a brain scan to check if you have PRES. If you do, they will stop treatment with gilteritinib. They will monitor you closely for any signs of PRES so they can treat it quickly if it happens.

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Pregnancy, breastfeeding and fertility

Gilteritinib tablets may harm unborn babies.

- If you could get pregnant, it is important to use effective contraception while you are taking gilteritinib and for at least 6 months after you stop. The treatment might affect hormonal contraceptive pills or devices, so it's important to use a barrier method like a condom, diaphragm or cap.

- If you could make someone pregnant, it is important to use effective contraception while you are taking gilteritinib and for at least 4 months after you stop.
- If you are taking gilteritinib and think you might be pregnant, tell your haematology team as soon as possible. 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, tell your haematology team. They can discuss your treatment options with you.

Breastfeeding

Scientists are not sure if gilteritinib passes into breast milk. If it does, it could be a risk for breastfed babies or children. You should not breastfeed when taking gilteritinib.

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Monitoring

During your treatment with gilteritinib you will have blood tests:

- Before you start treatment
- 15 days after you start treatment
- Every month after that

You will also have heart test and scans:

- Before you start treatment
- 8 days and 15 days after you start treatment
- Every 3 months after that

You may also have further blood, bone marrow and heart tests and scans during your treatment. Your haematology team will let you know what tests you will need and how often.

Your haematology team will use the results of these tests to:

- Check how well gilteritinib is working for you
- Make sure your blood counts have not dropped too low
- Check the level of salts in your blood
- Check how well your heart is working

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How long to take gilteritinib

You usually carry on taking gilteritinib tablets unless:

- They stop working well
- You are having side effects that are difficult to cope with

If this happens, your haematology team might stop gilteritinib, adjust your dose or recommend a different treatment.

> **Do not stop taking gilteritinib tablets without talking to your haematology team.**

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Side effects

You may get some side effects while you are taking gilteritinib tablets. Some people may have very few side effects, whereas other people experience more serious side effects.

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

If you are getting side effects that are difficult to cope with, your haematology team might suggest:

- Temporarily stopping treatment
- Lowering your dose of gilteritinib

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Serious side effects

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

Serious side effects of gilteritinib include:

- Unexpected bruising or bleeding, like nosebleeds, bleeding gums, blood spots or rashes, due to a low platelet count.
- Feeling tired, dizzy or short of breath, due to a low red blood cell count (anaemia).
- A high temperature (37.5°C to 38°C or higher) with a low white blood cell count. This is called febrile neutropenia. You might also feel shivery or generally unwell.
- Liver or kidney problems.
- Diarrhoea.
- Shortness of breath.
- Low blood pressure.
- Changes in the electrical activity in your heart (seen on a heart tracing or ECG).
- Differentiation syndrome.
- Posterior reversible encephalopathy syndrome.

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Very common side effects

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

Very common side effects include:

- Dizziness
- Cough
- Feeling sick
- Constipation
- Pain in your joints, muscles, hands or feet
- Pain in your legs, ankles, feet, arms, shoulders, wrists or hands

- Fatigue
- Swollen feet or ankles
- Weakness or lack of energy
- Changes in the levels of some chemicals in your blood (found on blood tests)

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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 gilteritinib tablets.

Common side effects include:

- Feeling generally unwell
- Chest pain, breathlessness, dizziness or swollen feet and ankles due to problems with your heart
- An unusual allergic reaction, which can cause swelling of your throat and tongue, difficulty breathing, fainting and dizziness.

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If gilteritinib does not work

If gilteritinib is not working well, your haematology team might suggest increasing your dose after 4 weeks to 200mg once a day.

If this is not suitable for you, or does not work, they will talk to you about your treatment options.

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Sources we used to develop this information

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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.

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Page last reviewed: 31 January 2025
Updated February 2026
Next review due: 31 January 2028

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