

Venetoclax + azacitidine

Venetoclax + azacitidine is a combination of medicines used to treat some people with acute myeloid leukaemia (AML).

Summary

- Venetoclax + azacitidine is a combination of medicines used to treat some adults with acute myeloid leukaemia (AML).
 - Venetoclax is a targeted medicine. It comes as film-coated tablets that you take by mouth.
 - Most people start on a low dose of venetoclax. Usually, your doctor will increase the dose every day for 3 days until you reach the full dose.
 - Azacitidine is a type of chemotherapy medicine. You have it as an injection just under your skin, usually in your tummy, thigh or upper arm.
 - You have treatment in 4-week cycles, with 7 days when you have injections and 21 days when you don't.
- You will have regular blood tests 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 venetoclax + azacitidine. 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 a high temperature (over 38°C), feel shivery or generally unwell.
 - You have a cough, chest pain or wheezing, a high temperature, an aching body, feel very tired or lose your appetite.
 - You are feeling confused, slurring your words or not making sense.
 - You have blue, grey, pale or blotchy skin, lips or tongue. This may look different on brown or black skin.
 - You have a rash that doesn't fade when you roll a glass over it.
 - You have difficulty breathing, shortness of breath or breathing very fast.

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About venetoclax + azacitidine

Your haematology team might recommend venetoclax + azacitidine for you if:

- You are newly diagnosed with AML **AND**
- Intensive chemotherapy is not suitable for you

Sometimes venetoclax may be given with other medicines instead of azacitidine, such as low-dose cytarabine. Your medical team will let you know which combination of medicines you are taking.

We have separate [information about venetoclax for CLL or combined with other medicines](#).

Venetoclax

Venetoclax is a targeted medicine that blocks a protein called BCL-2. This protein is present in some cancer cells. Blocking it can help kill cancer cells.

The brand name for venetoclax is Venclyxto.

Azacitidine

Azacitidine is a chemotherapy medicine that can turn on genes that have been turned off. This includes cancer-suppressing genes that are often turned off in AML cells. Azacitidine can also stop AML cells making proteins, which can stop cancer cells growing and dividing.

Brand names for azacitidine injections include:

- Azacitidine betapharm
- Azacitidine Sandoz
- Azacitidine Seacross
- Azacitidine Tillomed
- Vidaza

[Back to top](#)

Before having venetoclax + azacitidine

Before starting venetoclax + azacitidine, your haematology team will carry out checks to make sure it is suitable for you. These might include:

- Blood tests to measure your blood counts
 - If your white blood cell count is too high, you might have treatment to lower it before starting venetoclax + azacitidine
- Blood tests to check your liver and kidney function, and the levels of salts in your body
- Bone marrow test

Things to tell your haematology team

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

- Have kidney disease or liver disease
- Have ever had a heart attack or heart condition
- Have a history of lung disease
- Have an infection, or have had a long-lasting or repeated infection

Some medicines or drugs may interact with venetoclax. 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:

- Herbal medicines, such as St John's Wort
- Some antibiotic, antifungal and antiviral medicines
- Some medicines used to treat epilepsy
- Some medicines used to treat high blood pressure (including high blood pressure in your lungs)
- Modafinil, a medicine used to treat sleeping disorders
- Digoxin, a medicine used to treat heart failure or abnormal heart rhythms
- Dabigatran, a medicine used to treat and prevent blood clots and stroke

Studies in animals found that venetoclax might cause a low or no sperm count. Scientists do not know if this is the same for humans. If you were born male and

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you may want to have children in the future, ask your haematology team for advice on sperm storage before starting treatment.

[Back to top](#)

Having venetoclax + azacitidine

You will receive treatment in a cycle of 28 days. This is made up of some days where you will have venetoclax + azacitidine, and some days where you only have venetoclax.

Having venetoclax

Venetoclax comes as film-coated tablets containing 10mg, 50mg or 100mg of venetoclax. The number of tablets you take depends on the dose and strength of the tablets. 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 venetoclax as prescribed so it can work as well as possible. Try and take it with food at the same time of day if you can.
- Swallow the venetoclax 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.
- Your doctor will give you tablets to control your uric acid levels. You usually need to take these during the first 3 to 4 days of treatment while your venetoclax dose is being increased. Sometimes you may need to take them for longer.
- Drink plenty of water, especially during the first few days of treatment. This reduces the risk of getting side effects from the breakdown of cancer cells.
- 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 venetoclax dose:
 - And it is **less than 8 hours** since the time you usually take your dose, take it as soon as possible.
 - And it is **more than 8 hours** since the time you usually take your dose, do not take a dose that day. Take your normal dose at the normal time the next day.

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Having azacitidine

You usually have azacitidine injections in a treatment cycle of 28 days. Depending on how you cope with treatment, and how well it works, your doctor might make some changes to the length of your treatment cycle or how many days you have injections.

- You usually have azacitidine injections on 7 days at the start of each cycle. This is usually 5 days of treatment, a weekend off, then another 2 days of treatment.
- For the rest of your treatment cycle, you do not have azacitidine injections.
- You usually have the injection at a hospital day unit and go home the same day.
- Your doctor will give you tablets to help stop you feeling sick or being sick. You usually take these 30 minutes before you have your azacitidine injection.
- Your doctor or nurse will give you the injection just under your skin in your tummy, thigh or upper arm.

Dose

Your haematology team will let you know what dose you are on, but below are the most common doses that are used.

Venetoclax

You start on a low dose of venetoclax. Your doctor usually increases the dose every day for 3 days until you reach the full dose. Most people have:

- Day 1: 100mg once a day
- Day 2: 200mg once a day
- Day 3 onwards: 400mg once a day

Azacitidine

Your doctor will work out the best dose of azacitidine for you based on your height, weight and how well you respond to treatment. They will tell you what dose they recommend for you.

[Back to top](#)

Precautions

There are several precautions to be aware of when you are taking venetoclax + azacitidine.

- Do not eat, drink or use supplements that contain – grapefruit, Seville oranges (usually used in marmalade) or starfruit. This is because they can increase the amount of venetoclax in your blood.
- Azacitidine injections may make you feel tired or weak or make it difficult to concentrate. Take care if you are driving or using tools or machinery.
- Azacitidine can affect how well your kidneys work. If you stop peeing, or you're peeing less than usual, tell your doctor straight away.
- Tell your haematology team if you are due to have any vaccines.

[Back to top](#)

Pregnancy, breastfeeding and fertility

Venetoclax + azacitidine may harm unborn babies.

- If you could get pregnant, it is important to use effective contraception. You need to do this while you are having venetoclax + azacitidine and for 6 months after you stop. The treatment might affect hormonal contraceptive pills or devices. So it is 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. You need to do this while you are having venetoclax + azacitidine and for at least 3 months after you stop.
- If you think you might be pregnant, tell your haematology team as soon as possible. They may recommend stopping venetoclax + azacitidine for a while. They could also recommend 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 venetoclax + azacitidine passes into breast milk. If it does, it could be a risk for breastfed babies or children. You should not breastfeed when taking venetoclax + azacitidine.

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[Back to top](#)

Monitoring

During your treatment with venetoclax + azacitidine you will have regular blood tests.

These are usually:

- Before you start treatment
- After each new dose of venetoclax when your dose is being gradually increased
- After reaching your full dose of venetoclax
- Before starting each cycle of treatment with azacitidine

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

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

- Check how well venetoclax + azacitidine is working for you
- Make sure your blood counts have not dropped too low
- Check how well your liver and kidneys are working
- Check the level of salts in your blood

Tumour lysis syndrome

Venetoclax + azacitidine kills cancer cells. When lots of cancer cells breakdown quickly, they can release a large amount of chemicals into your blood. This is known as tumour lysis syndrome. It can affect how well your kidneys work, as well as causing changes to your heartbeat and sometimes fits (seizures). It happens to around 1 in every 100 people having venetoclax + azacitidine. This means 99 in every 100 do not get it.

If you have a very high leukaemia cell count before treatment, your haematology team may consider admitting you for the first week of treatment and might give you medicine to help prevent tumour lysis syndrome. Making sure you stay well hydrated and drinking plenty of water with your tablets can also help prevent tumour lysis syndrome. Your team will monitor you closely so they can treat it quickly if it happens. They may pause treatment for a while or adjust your dose.

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Differentiation syndrome

Very rarely, azacitidine injections might cause a serious problem called differentiation syndrome. This can happen if recovering white blood cells release too many immune chemicals, which can trigger a severe reaction.

Your haematology team will monitor you for signs of differentiation syndrome. If it happens, it can be treated with steroids.

[Back to top](#)

How long to have this treatment

You usually carry on having venetoclax + azacitidine unless:

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

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

Do not stop taking venetoclax + azacitidine without talking to your haematology team.

[Back to top](#)

Side effects

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

Tell your haematology team about any side effects you have. They may be able to suggest things you can do or give you medicines to help.

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

- Temporarily stopping treatment
- Lowering your dose of venetoclax + azacitidine
- Delaying your next azacitidine treatment cycle

[Back to top](#)

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.

The most common serious side effects for people having venetoclax + azacitidine include:

- A high temperature (higher than 38°C) with a low white blood cell count (febrile neutropenia). You might also feel shivery or generally unwell.
- Pneumonia (a lung infection). You may get symptoms like:
 - A cough, chest pain, shortness of breath, wheezing.
 - A high temperature.
 - An aching body, feeling very tired, loss of appetite.
- Sepsis, which is a life-threatening reaction to an infection. You may get symptoms like:
 - Feeling confused, slurring your words, not making sense.
 - Blue, grey, pale or blotchy skin, lips or tongue. This may look different on black or brown skin.
 - A rash that doesn't fade when you roll a glass over it.
 - Difficulty breathing, shortness of breath or breathing very fast.

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Venetoclax + azacitidine can lower your blood cell counts. This can make you more likely to get infections, fever, bruising, bleeding, shortness of breath or feeling very tired. If you get any of these symptoms, tell your doctor or nurse straight away.

[Back to top](#)

Most common side effects

Most common side effects affect more than 20 in every 100 people who are having venetoclax + azacitidine. Most common side effects include:

- A low platelet count, which might lead to unexpected bruising or bleeding like nosebleeds, bleeding gums, blood spots or rashes
- A low white blood cell count, which might mean that you get infections more often and any infections you get might last longer than usual
- A low red blood cell count (anaemia), which can make you feel tired, dizzy or short of breath
- Low potassium levels which can cause muscle weakness, muscle cramps and a fast and irregular heartbeat
- A build up of fluid, in your legs, ankles and feet and sometimes your arms and hands
- An irregular, pounding, fluttering or fast heartbeat
- Fever
- Fatigue
- Decreased appetite
- Feeling sick or being sick
- Diarrhoea
- Constipation

Constipation can also be a side effect of anti-sickness medicines you have with azacitidine. If you are constipated, tell your haematology team. They may be able to adjust your anti-sickness medication to help with this.

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[Back to top](#)

If this treatment does not work

If venetoclax + azacitidine are not working well, your haematology team might suggest altering your treatment cycle, your dose, or stopping treatment if your blood counts drop.

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

[Back to top](#)

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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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