

# Ivosidenib + azacitidine

Acute myeloid leukaemia (AML) is a fast-growing blood cancer that involves the white blood cells. Ivosidenib + azacitidine is a combination of medicines used to treat AML. We cover what ivosidenib + azacitidine is, who might have it, and how to have it. We also cover its main side effects and any special precautions you may need to take while you're on it.

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Throughout this leaflet, you will see QR codes and URLs that link to webpages for further support. If you are not able to access the webpages, please email [information@leukaemiacare.org.uk](mailto:information@leukaemiacare.org.uk) or call 01905 755977.

## Summary

- Ivosidenib + azacitidine is a combination of medicines. They are used to treat some adults with acute myeloid leukaemia (AML).
- Ivosidenib is a targeted medicine. It comes as film-coated tablets that you take by mouth.
- Azacitidine is a type of chemotherapy medicine. You have it as an injection just under your skin. You usually have it in your tummy, thigh or upper arm.
- 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 having ivosidenib + 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 fever, cough, shortness of breath, wheezing or chest pain
  - You have swelling of your arms, legs and neck or weight gain
  - You are feeling or being sick or feeling very tired
  - You get unexpected bruising or bleeding like nosebleeds, bleeding gums, blood spots or rashes

## About ivosidenib + azacitidine

Ivosidenib is a targeted medicine. It blocks an abnormal version of a protein called IDH1. This abnormal protein can stop cells growing properly. This can lead to the development of cancer. Blocking the protein can help kill cancer cells.

The brand name for ivosidenib is Tibsovo.

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 from making proteins. This can stop cancer cells growing and dividing.

Brand names for azacitidine injections include:

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

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

- You are newly diagnosed with AML **AND**
- You have a genetic change in a gene called *IDH1* **AND**
- Intensive chemotherapy is not suitable for you

## Before having ivosidenib + azacitidine

Before starting treatment, tell your medical team if you have heart, kidney or liver problems. This is because ivosidenib can affect how your heart, kidneys and liver work.

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

- A heart tracing (ECG) to check the electrical activity of your heart
- Blood tests to measure your blood counts
- Blood tests to check your liver and kidney function
- Bone marrow tests
- A pregnancy test



Some medicines or drugs may interact with ivosidenib. It is important to tell your team about any medicines you are taking. This includes medicines you have bought yourself, without a prescription. Examples include:

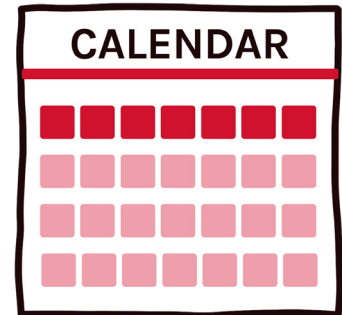
- Some antibiotic, antifungal and antiviral medicines
- Some medicines used to lower your cholesterol levels
- Some medicines used after organ transplants, known as immunosuppressants
- Some medicines to help stop you feeling or being sick
- Some medicines used for cancer
- Some medicines that affect your heartbeat
- Some medicines used for type 2 diabetes
- Warfarin, a medicine used to prevent blood clots
- Some medicines used to treat severe pain or to stop you feeling pain in surgery
- Pimozide, a medicine used to treat schizophrenia
- Methadone, a medicine used for severe pain, or morphine or heroin addiction
- Omeprazole, a medicine used to treat stomach ulcers and acid reflux
- Furosemide, a medicine used to treat a build up of fluid known as oedema
- Lamotrigine, a medicine used to treat epilepsy

## Having your treatment

You will receive treatment in a cycle of 28 days. On some days you will have ivosidenib + azacitidine. On some days you will only have ivosidenib.

Ivosidenib comes as film-coated tablets containing 250mg of ivosidenib. 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 ivosidenib as prescribed so it can work as well as possible. Try and take it at the same time of day if you can.
- Take the tablets **without food**. You should not eat anything from **2 hours before** to **1 hour after** taking the tablets.
- Do not have grapefruit or grapefruit juice while you are taking ivosidenib. This is because it can affect how the medicine is absorbed by your body.
- Swallow the ivosidenib tablets whole with a full glass of water. To make sure you get the right dose, do not break, crush, dissolve or chew the tablets.
- Take care to not swallow the silica gel packet found in the bottle. It helps protect the tablets from moisture.
- 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 ivosidenib dose:
  - And it is **less than 12 hours** since the time you usually take your dose, take it as soon as possible.
  - And it is **more than 12 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.



You usually have azacitidine injections in a treatment cycle of 28 days. Your doctor might adjust the cycle based on how you cope with treatment and how well it works. They could change the length of the cycle or how many days you have injections.



- You usually have azacitidine injections over 7 days at the start of the cycle. This is usually 5 days of treatment, a weekend off, then another 2 days of treatment.
- For the rest of the 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. You usually have it in your tummy, thigh or upper arm.

## **Dose**

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

### Ivosidenib

Most adults with AML take two 250mg ivosidenib tablets every day. You usually take both at the same time each day.

Your medical team may suggest a different dose. This will depend on your circumstances and any other medicines you are taking. They will tell you what dose they recommend for you.

### Azacitidine

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

## Precautions when having ivosidenib + azacitidine

There are several precautions to be aware of when you are having your treatment.

- Azacitidine injections may make you feel tired or weak. They can also 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.

## Pregnancy, breastfeeding and fertility

Ivosidenib + 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 ivosidenib + 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 ivosidenib + azacitidine and for 3 months after you stop.
- If you think you might be pregnant, tell your medical team as soon as possible. They may recommend stopping ivosidenib + 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 medical team. They can discuss your treatment options with you.

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

## Monitoring during your treatment

During your treatment with ivosidenib + azacitidine you will have:

- Regular blood tests
- A heart tracing (ECG) every week at first, and then every month

You may also have occasional bone marrow tests or other tests. Your medical team will let you know what tests you will need and how often.

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

- Check how well ivosidenib + 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 electrical activity of your heart
- Check the levels of salts in your blood

### Differentiation syndrome

Ivosidenib + azacitidine might sometimes cause a serious problem called differentiation syndrome. This can happen if recovering white blood cells release too many immune chemicals. This can trigger a severe reaction.

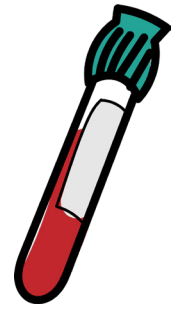
Your medical team will monitor you for signs of differentiation syndrome. If it happens, it can be treated with steroids.

## How long to have your treatment

You usually carry on having ivosidenib + 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 doctor might adjust your dose, stop your treatment or suggest different treatment.



## Side effects of your treatment

You may get some side effects while you are having ivosidenib + azacitidine.

Some people may have very few side effects, whereas other people experience more serious side effects.

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

Ivosidenib is a fairly new medicine. It is being monitored more closely than older medicines to help identify new safety information. If you get any side effects that you think are due to ivosidenib, you can report them directly via the [Yellow Card Scheme](#). Follow the link, scan the QR code, or search 'ivosidenib' at [yellowcard.mhra.gov.uk](http://yellowcard.mhra.gov.uk)



### Serious side effects of ivosidenib + azacitidine

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 ivosidenib + azacitidine include:

- Differentiation syndrome ([page 8](#)). This can cause symptoms like:
  - Fever, cough, shortness of breath, wheezing.
  - Weight gain.
  - Swelling of your arms, legs and neck.
  - A build up of fluid around your heart. This can cause shortness of breath, difficulty breathing when lying down and chest pain.
  - A build up of fluid around your lungs which can cause chest pain, cough and shortness of breath.
  - Low blood pressure.
  - Kidney failure which can cause you to be sick or feel tired or exhausted.
- A low platelet count. This might lead to unexpected bruising or bleeding, like nosebleeds, bleeding gums, blood spots or rashes.

Ivosidenib + 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.

## Other side effects

You may experience some of the following common side effects when having ivosidenib + azacitidine. Tell your medical 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 medical team might suggest:

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

## Very common side effects

**Very common side effects** affect more than 10 in every 100 people who are having ivosidenib + azacitidine.

Very common side effects include:

- A low level of some white blood cells. This makes you more likely to get infections and can mean that any infections you do get are more serious.
- A high level of some other white blood cells.
- Finding it hard to fall asleep or stay asleep.
- Headache.
- Dizziness.
- Being sick.
- Pain in your arms, wrists, shoulders or hands.
- Pain in your legs, ankles or feet.
- Joint pain.
- Back pain.
- Your heart taking longer to recover after each heartbeat. This might show on an ECG or might cause symptoms such as:
  - Blackouts, fainting or losing consciousness.
  - Fits (seizures).
  - A fast, irregular heartbeat.



## Common side effects

**Common side effects** affect more than 1 but less than 10 out of every 100 people who are having ivosidenib + azacitidine.

Common side effects include:

- A low level of some white blood cells
- Nerve damage. This can cause symptoms like:
  - Numbness and tingling in your feet or hands
  - Burning, stabbing or shooting pain in your legs, feet, arms or hands
  - Loss of balance and co-ordination
  - Muscle weakness, especially in your feet
- Painful mouth or throat



## **Treatment options if ivosidenib + azacitidine does not work**

If ivosidenib + azacitidine are not working well, your medical team might suggest:

- Altering your treatment cycle
- Changing your dose
- 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.

## Further information

We have more [information about AML](#) including booklets and factsheets to download. Follow the link, scan the QR code or search 'AML' at [leukaemiacare.org.uk](https://leukaemiacare.org.uk)



We also have [booklets you can order in print free of charge](#). Follow the link or search 'AML' at [shop.leukaemiacare.org.uk](https://shop.leukaemiacare.org.uk) or scan the QR code.



We are grateful to Renuka Palanicawandar, haematologist, and Catherine Langton, clinical nurse specialist and Sue, patient reviewer, 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](mailto:information@leukaemiacare.org.uk)
- Complete our [short survey](#) to help us improve our information
- 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](https://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**

