

Midostaurin

Midostaurin is a targeted medicine used to treat some people with acute myeloid leukaemia (AML).

Summary

- Midostaurin is used to treat some people with acute myeloid leukaemia (AML).
- Midostaurin is a medicine that blocks a protein to help stop cancer cells from growing and dividing.
- It comes as capsules that you take by mouth. Your haematology team will tell you how many to take and how often.
- 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 midostaurin. 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 (higher than 38°C), feel shivery or generally unwell
 - You are getting infections more often and any infections you get last longer than usual
 - You have infections around your drip, central line or any catheters you have
 - You have redness, peeling, scaly-looking, itchy skin (this may look different on black or brown skin)
 - You have high blood sugar which can make you feel thirsty, hungry, and cause fatigue and peeing more often
 - You are feeling sick

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<https://lcdemo-stage.gb.aldryn.io/about-leukaemia/treatments/midostaurin/>

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Helpline: [0808 010 444](tel:0808010444)

About midostaurin

Midostaurin is a targeted medicine that blocks a protein leukaemia cells use to grow and divide. This protein is called FLT3. Midostaurin can also target some other proteins but with lower activity.

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 midostaurin is Rydapt.

Who might have midostaurin?

Your haematology team might recommend midostaurin for you if:

- You have been newly diagnosed with AML **AND**
- Your leukaemia cells have a change in the *FLT3* gene

Midostaurin can be given alongside chemotherapy or used on its own, depending on the phase of treatment you are having.

- For induction: You have midostaurin along with daunorubicin + cytarabine
- For consolidation: You have midostaurin along with high-dose cytarabine
- For maintenance: You have midostaurin on its own

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Before taking midostaurin

Before starting midostaurin, 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
- Blood tests to check the levels of salts in your blood
- Bone marrow tests
- Tests to check your heart and lung function
- A pregnancy test

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Things to tell your haematology team

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

- Have any allergies, or have ever had an allergic reaction
- Have any infections
- Have any problems with your heart
- Have any problems with your lungs or problems with your breathing
- Are or think you may be pregnant

Some medicines or drugs may interact with midostaurin. 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 to treat tuberculosis (TB)
- Some medicines to treat epilepsy
- Some medicines used to treat infections
- Some medicines used to treat HIV
- Some medicines used to treat depression
- Some medicines used to control the levels of fat or cholesterol in your blood
- Tizanidine, a medicine used to relax muscles
- Chlorzoxazone, a medicine used to treat discomfort caused by muscle spasms
- Enzalutamide, a medicine used to treat prostate cancer
- Herbal medicines, such as St John's Wort

Animal studies have shown that midostaurin may affect your fertility. If you may want to have children in the future, ask your haematology team for advice on sperm or egg storage before starting treatment.

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Taking midostaurin

Midostaurin is used as part of intensive treatment for AML.

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During **induction and consolidation**, you have midostaurin combined with [daunorubicin + cytarabine](#) or [high-dose cytarabine](#). You may need to stay in hospital while you have treatment and until your blood counts recover. Or, you may have chemotherapy on a day unit and go home each day. Your haematology team will let you know what they recommend for you. You may be able to take midostaurin at home.



During the **maintenance phase**, you have midostaurin on its own at home.

When you are on midostaurin:

- Your doctor may also give you tablets to help stop you feeling sick or being sick. They will let you know if you need to take them and how to take them.
- You should take midostaurin as prescribed so it can work as well as possible. Taking the capsules at the same time of day can help you remember to take it.
- You should take the capsules with food twice a day about 12 hours apart (for example with breakfast and with your evening meal).
- Swallow the midostaurin capsule whole with a full glass of water. To make sure you get the right dose, do not break, crush, dissolve or chew the capsule.
- If you are sick after taking a capsule, do not take another dose. Instead, wait until your next dose and take it as normal. It is important not to take a double dose.
- If you forget to take your capsules, skip this dose and take your next dose at the usual time. Do not take a double dose to make up for a forgotten capsule.
- If you take too many capsules, talk to a doctor or go to hospital straight away. Take the medicine packaging with you, as you might need treatment.

During induction and consolidation you have treatment in cycles, with time in between for your blood counts to recover. You have different medicines on different days.

First induction

A common schedule is:

- Day 1: Daunorubicin + cytarabine
- Day 2: Cytarabine
- Day 3: Daunorubicin + cytarabine
- Day 4: Cytarabine

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- Day 5: Daunorubicin + cytarabine
- Day 6 to 10: Cytarabine
- Day 11 to 25: Midostaurin

You usually have cytarabine and daunorubicin through a drip into a vein (or a central line if you have one).

You will usually need to stay in hospital while you are having chemotherapy, but you may be able to have some as an outpatient.

You usually take midostaurin at home for the rest of your treatment cycle.

Second induction

A common schedule is:

- Day 1: Daunorubicin + cytarabine
- Day 2: Cytarabine
- Day 3: Daunorubicin + cytarabine
- Day 4: Cytarabine
- Day 5: Daunorubicin + cytarabine
- Day 6 to 8: Cytarabine
- Day 9 to 23: Midostaurin

You usually have cytarabine and daunorubicin through a drip into a vein (or a central line if you have one).

You will usually need to stay in hospital while you are having chemotherapy, but you may be able to have some as an outpatient.

You usually take midostaurin at home for the rest of your treatment cycle.

Consolidation

A common schedule is:

- Day 1: High-dose cytarabine
- Day 2: No treatment
- Day 3: High-dose cytarabine
- Day 4: No treatment
- Day 5: High-dose cytarabine
- Day 6 to 20: Midostaurin

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You have cytarabine as a drip into a vein (or a central line if you have one) over 3 hours, every 12 hours. You usually need to stay in hospital while you are having chemotherapy, but you may be able to have some as an outpatient.

You will be given midostaurin to take at home for the rest of your treatment cycle.

Maintenance

You take midostaurin as capsules, twice a day, each day.

Dose

Most adults with AML take two 50mg midostaurin capsules a day.

Your haematology team may suggest a different dose, depending on your circumstances. They will tell you what dose they recommend for you. Your dose should also be printed on the named label on the medicine packaging. If you are not sure, ask your doctor or nurse.

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Precautions

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

- Midostaurin may cause dizziness and vertigo. Take care if you are driving or using tools or machinery.
- Do not eat or drink grapefruit or grapefruit juice while taking midostaurin. This is because grapefruit can affect how much midostaurin your body absorbs.

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Pregnancy, breastfeeding and fertility

Midostaurin may harm unborn babies.

- If you could get pregnant, it is important to use effective contraception. You need to do this while you are taking midostaurin and for 4 months after you stop.
- If you think you might be pregnant, tell your haematology team as soon as possible. They may recommend stopping midostaurin for a while. They could also recommend switching to a different treatment.

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- If you are planning to get pregnant, tell your haematology team. They can discuss your treatment options with you.

Breastfeeding

Midostaurin could be a risk for breastfed babies or children. You should not breastfeed when taking midostaurin and for at least 4 months afterwards.

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Monitoring

During your treatment with midostaurin you will have blood tests:

- Before you start your treatment
- After each treatment cycle
- Regularly throughout your treatment

You may also have bone marrow tests, heart tests, lung tests and other tests. 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 midostaurin is working for you
- Make sure your blood counts have not dropped too low
- Check how well your heart and lungs are working

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How long to have midostaurin

The number of cycles you have depends on how you respond to treatment and how well your body is coping with it.

You are likely to have one or two cycles of induction therapy, one or two cycles of consolidation therapy and up to 1 year of maintenance therapy.

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Side effects

Like all medicines, midostaurin can cause side effects. Some of these may be serious. Side effects are different for everyone, and we cannot predict what side effects you may or may not get.

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:

- Lowering your dose of midostaurin
- Changing how often you have midostaurin
- Stopping midostaurin treatment

Midostaurin is a fairly new medicine, so it is being monitored more closely than older medicines. This helps identify new safety information. If you get any side effects that you think are due to midostaurin, you can report them directly via the [Yellow Card Scheme](#).

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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.

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Your medical team will closely monitor you for serious side effects so that they can treat them promptly if they happen. The most important serious side effects for people taking midostaurin are:

- A high temperature (higher than 38°C) with a low white blood cell count. This is called febrile neutropenia. You might also feel shivery or generally unwell.
- Frequent or long-lasting infections due to a low white blood cell count.
- Infections around your drip, central line or any catheters you have.
- Inflammation of your skin which can cause redness, peeling, scaly looking skin and itching (this may look different on black or brown skin).
- High blood sugar which can make you feel thirsty, fatigue, peeing more often and feeling hungry.
- Feeling sick.

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Very common side effects

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

Very common side effects include:

- Feeling sick or being sick (talk to your medical team about different ways to manage this if you are struggling)
- Reddish purple pinpoint round spots under the skin (this may look different on black or brown skin)
- Sneezing, itchy eyes
- Finding it hard to get to sleep or stay asleep
- Headache
- Low blood pressure
- Nosebleeds
- Hoarseness, losing your voice, sore throat
- Cough, chest pain and difficulty breathing
- Shortness of breath
- Pain or a burning sensation around your mouth, redness around your mouth, blisters and swelling
- Pain in your upper tummy

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- Piles which can cause blood in your poo, an itchy or painful bottom, and mucus coming from your bottom
- Excessive sweating
- Back pain
- Joint pain
- Fever
- Your heart taking longer to recover after heartbeats, which can cause fast heart rate, fits and fainting
- Feeling tired, dizzy or short of breath due to a low level of red blood cells
- Changes in the levels of salts in your blood
- Changes in your liver function (found on blood tests)
- Your blood taking longer to clot than usual

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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 midostaurin.

Common side effects include:

- Blocked or runny nose
- A high level of uric acid in your blood, which can cause gout
- Fainting (loss of consciousness)
- Uncontrolled shaking or twitching of parts of your body, mainly affecting your hands, arms, eyes, face, head or legs
- Swollen eyelids
- High blood pressure
- Dizziness
- Struggling to speak and tightness in your chest
- Pain or discomfort in your tummy
- Dry skin
- Inflammation of your eye which can cause eye pain, redness, tears or discharge from your eye, blurred vision and sensitivity to light
- Bone pain
- Pain in your hands, arms, feet or legs

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- Neck pain
- A blood clot due to a catheter, which can cause pain, swelling and discolouration of your arm
- A high level of calcium in your blood which can cause you to feel sick, be sick, lack of appetite, feeling thirsty, peeing more often and muscle weakness
- Weight gain

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What to do if you get side effects

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

- Giving you medicines like antibiotics, antifungals or antivirals to treat and prevent infections
- Giving you supplements if you have a low level of salts or minerals in your blood
- Having blood transfusions if you have a low level of blood cells
- Mouthwashes, rinses and gels to help with sore mouth
- Medicines to prevent and treat sickness and diarrhoea
- A drip if you're not getting enough fluid

[Blood Cancer UK](#) and [Macmillan](#) have more information on coping with side effects and treatment.

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If midostaurin does not work

If midostaurin is not working well, your haematology team might suggest altering how often you have treatment or changing the dose of treatments you are having with midostaurin.

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

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If your AML does not respond to treatment, this is known as refractory AML. We have more [information about relapsed and refractory AML](#).

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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 December 2024

Updated February 2026

Next review due: 31 December 2027

