

AZACITIDINE ACCORD

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Azacitidine Accord?

Azacitidine Accord contains the active ingredient azacitidine. Azacitidine Accord is used for the treatment of myelodysplastic syndrome (MDS). Myelodysplastic syndrome is a blood disorder in which the bone marrow is not working normally and does not produce enough mature blood cells. This causes a lack of healthy blood cells that can function properly in the body.

For more information, see Section [1. Why am I using Azacitidine Accord?](#) in the full CMI.

2. What should I know before I use Azacitidine Accord?

Do not use if you have ever had an allergic reaction to azacitidine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Azacitidine Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Azacitidine Accord and affect how it works.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Azacitidine Accord?

Azacitidine Accord is an injection and will be given to you by your doctor or nurse.

More instructions can be found in Section [4. How do I use Azacitidine Accord?](#) in the full CMI.

5. What should I know while using Azacitidine Accord?

Things you should do	<ul style="list-style-type: none">• Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Azacitidine Accord• Tell your doctor immediately if you stop passing urine or if you are passing less urine than normal• If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with this medicine• If you become pregnant while taking this medicine, tell your doctor immediately• Keep all your doctor's appointments so that your progress can be checked. Your doctor will do some tests e.g. blood tests, at regular intervals to make sure the medicine is working and to prevent any unwanted side effect
Driving or using machines	Be careful driving or operating machinery until you know how Azacitidine Accord affects you.

For more information, see Section [5. What should I know while using Azacitidine Accord?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the common and serious side effects are included in full below in the CMI. Speak to your doctor if you have any of these common or serious side effects and they worry you.

The very serious side effects are:

- Shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching or hives on the skin.
- A sudden severe headache; weakness or numbness in the face, arm or leg; changes in vision; trouble speaking or understanding speech; or loss of coordination.
- Fever; chills; shortness of breath; cough; phlegm; or occasionally coughing up blood.
- Fever; severe chills; hot, tender and red skin; rapid breathing; rapid pulse; confusion; nausea; vomiting; diarrhoea; pain or burning when you urinate; sore mouth or throat; or mouth ulcers.
- Vomiting blood or material that looks like coffee grounds; bleeding from the back passage; black sticky bowel motions (stools); or bloody diarrhoea.
- Fever, cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain. These could be symptoms of a serious immune reaction (differentiation syndrome).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

AZACITIDINE ACCORD

Active ingredient: *azacitidine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Azacitidine Accord. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Azacitidine Accord.**

Where to find information in this leaflet:

- [1. Why am I using Azacitidine Accord?](#)
- [2. What should I know before I use Azacitidine Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Azacitidine Accord?](#)
- [5. What should I know while using Azacitidine Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Azacitidine Accord?

Azacitidine Accord contains the active ingredient azacitidine. Azacitidine is an anti-cancer agent. It is used to prevent the growth of cancer cells.

Azacitidine Accord is used for the treatment of myelodysplastic syndrome (MDS). Myelodysplastic syndrome is a blood disorder in which the bone marrow is not working normally and does not produce enough mature blood cells. This causes a lack of healthy blood cells that can function properly in the body.

2. What should I know before I use Azacitidine Accord?

Warnings

Do not use Azacitidine Accord if:

- you are allergic to azacitidine or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you can use this medicine

Check with your doctor if you have or have had:

- advanced liver cancer
- severe problems with your kidney function
- heart problems or lung disease
- allergies to any other medicines, foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Women: Avoid becoming pregnant while receiving Azacitidine Accord but if you do, tell your doctor immediately.

Use an effective method of contraception during treatment with Azacitidine Accord and for up to six months after discontinuation of Azacitidine Accord.

Do not breast-feed while you are receiving Azacitidine Accord but if you do, tell your doctor immediately.

It is not known if Azacitidine Accord is excreted in human milk.

Men: Do not father a child while receiving treatment with Azacitidine Accord.

Use barrier methods of contraception (e.g. condoms) during treatment and for up to three months after discontinuation of Azacitidine Accord, if your partner is of childbearing potential.

Talk to your doctor if you wish to conserve your sperm before having this treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Azacitidine Accord.

4. How do I use Azacitidine Accord?

How much to use

Azacitidine Accord will be given to you by a doctor or a nurse as an injection under the skin (subcutaneously i.e. under the skin on your thigh, abdomen or upper arm) or as an intravenous infusion.

Your doctor will decide what dose of Azacitidine Accord, the dose will depend on your general condition and your height and weight. Your dose will be calculated based on your body surface area, with the usual dose of 75 mg Azacitidine Accord per metre squared of body surface area.

Azacitidine Accord can cause nausea and vomiting. To stop you from getting sick (nausea and vomiting), your doctor may give you another medicine at the start of each treatment cycle with Azacitidine Accord.

When to use Azacitidine Accord

It is very important that you continue to receive Azacitidine Accord for as long as your doctor prescribes it.

You will have blood tests before you begin treatment with Azacitidine Accord and at the start of each period of treatment (called a 'cycle'). This is to check that you have enough blood cells and that your liver and kidneys are working properly.

Initially, Azacitidine Accord will be given daily for 7 days. 21 days later, you will have Azacitidine Accord for another 7 days. This is called a cycle. The cycle is repeated every 28 days for a minimum of 6 cycles.

Your doctor will check your progress and may change your dose if necessary.

If you are older than 65 years, your doctor will give you regular blood tests described above but may also check your kidney function during your treatment with other tests.

If you use too much Azacitidine Accord

It is unlikely that you will receive an overdose of Azacitidine Accord because a trained nurse or doctor will give it. If you think that you have been given too much Azacitidine Accord, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Azacitidine Accord?

Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Azacitidine Accord
- Tell your doctor immediately if you stop passing urine or if you are passing less urine than normal
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with this medicine
- If you become pregnant while taking this medicine, tell your doctor immediately
- Keep all your doctor's appointments so that your progress can be checked. Your doctor will do some tests e.g. blood tests, at regular intervals to make sure the medicine is working and to prevent any unwanted side effects

Driving or using machines

Be careful driving or operating machinery until you know how Azacitidine Accord affects you.

Looking after your medicine

The hospital will store Azacitidine Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Azacitidine Accord that may be left over.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> • sore throat or trouble swallowing, feeling of tension in the nose, cheeks or behind your eyes, runny or blocked nose • trouble sleeping, feeling tired or lacking energy, dizziness, headache, anxiety or feeling confused • loss of appetite, decreased weight, constipation, stomach pain, indigestion • cold sores or bleeding from the gums • red or purple, flat, pinhead spots under the skin, itching, rash, bruising, redness of the skin, soreness and swelling at the injection site, unusual hair loss or thinning • muscle or joint pain • chest pain 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Bleeding (including nosebleeds) or bruising in the absence of injury, or you are more tired than usual. Azacitidine Accord can reduce the number of red blood cells that carry oxygen around the body and can also reduce the number of platelets, which are responsible for making the blood clot appropriately. • Pain in one or both eyes, changes in vision. This could be due to bleeding in your eyes. • Blood in the urine. 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital</p>

Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"> • Shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching or hives on the skin. These could be symptoms of an allergic 	<p>Call your doctor straight away or go straight to the Emergency Department at</p>

<p>reaction.</p> <ul style="list-style-type: none"> • A sudden severe headache; weakness or numbness in the face, arm or leg; changes in vision; trouble speaking or understanding speech; or loss of coordination. These could be signs of bleeding in the brain (a type of stroke). • Fever; chills; shortness of breath; cough; phlegm; or occasionally coughing up blood. These could be symptoms of pneumonia (a serious lung infection). • Fever; severe chills; hot, tender and red skin; rapid breathing; rapid pulse; confusion; nausea; vomiting; diarrhoea; pain or burning when you urinate; sore mouth or throat; or mouth ulcers. These could be symptoms of sepsis (blood infection) or other frequent infections. • Vomiting blood or material that looks like coffee grounds; bleeding from the back passage; black sticky bowel motions (stools); or bloody diarrhoea. These could be signs of bleeding in your gut. • Fever, cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain. These could be symptoms of a serious immune reaction (differentiation syndrome). 	<p>your nearest hospital</p>
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What Azacidine Accord contains

Active ingredient (main ingredient)	azacidine
Other ingredients (inactive ingredients)	mannitol

Do not take this medicine if you are allergic to any of these ingredients.

What Azacidine Accord looks like

Azacidine Accord is a white powder supplied in glass vials. (100 mg Aust R 265774).

Who distributes Azacidine Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

This leaflet was prepared in August 2022.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.