

Azacitidine-Teva

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 given Azacitidine-Teva?

Azacitidine-Teva contains the active ingredient azacitidine. Azacitidine-Teva is used to treat 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.

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

2. What should I know before I am given Azacitidine-Teva?

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 am given Azacitidine-Teva?](#) in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given Azacitidine-Teva?

Azacitidine-Teva will be given to you in a hospital or clinic under the supervision of an experienced doctor.

More instructions can be found in Section [4. How am I given Azacitidine-Teva?](#) in the full CMI.

5. What should I know while receiving Azacitidine-Teva?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using Azacitidine-Teva.
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	<ul style="list-style-type: none"> • Tell your doctor immediately if you stop passing urine or if you are passing less urine than normal. • If you become pregnant while taking this medicine, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how Azacitidine-Teva affects you.

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

6. Are there any side effects?

Like all medicines, Azacitidine-Teva can have side effects, although not everybody gets them. Sometimes they may be serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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-Teva

Powder for injection

Active ingredient(s): azacitidine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Azacitidine-Teva. **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-Teva.**

Where to find information in this leaflet:

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

1. Why am I given Azacitidine-Teva?

Azacitidine-Teva contains the active ingredient azacitidine. Azacitidine-Teva is an anti-cancer agent, which prevents the growth of cancer cells.

Azacitidine-Teva has been prescribed by your doctor 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.

Ask your doctor if you have any questions about how Azacitidine-Teva works, or why this medicine has been prescribed for you.

Azacitidine-Teva will only be prescribed to you by a doctor who has experience in medicines to treat cancers of the blood.

2. What should I know before I am given Azacitidine-Teva?

Warnings

Do not use Azacitidine-Teva if:

- you are allergic to azacitidine or any of the ingredients of Azacitidine-Teva listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: 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.
- you have advanced liver cancer
- you are pregnant

- you have severe problems with your kidney function
- Always check the ingredients to make sure you can use this medicine

Check with your doctor if you:

- have any other medical conditions
- have had heart problems or lung disease
- take any medicines for any other condition

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

Check with your doctor if you are pregnant or intend to become pregnant.

Avoid becoming pregnant while receiving Azacitidine-Teva but if you do, tell your doctor immediately.

Use an effective method of contraception during treatment with Azacitidine-Teva and for up to six (6) months after discontinuation of Azacitidine-Teva.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed while you are receiving Azacitidine-Teva but if you do, tell your doctor immediately. It is not known if Azacitidine-Teva is excreted in human milk.

Use by men

- Do not father a child while receiving treatment with Azacitidine-Teva. Use barrier methods of contraception (e.g. condoms) during treatment and for up to three (3) months after discontinuation of Azacitidine-Teva, if your partner is of childbearing potential. Talk to your doctor if you wish to conserve your sperm before having this treatment.

Use by all patients

Tell your doctor if you have any allergies to any other medicines, foods, preservatives, or dyes.

Do not give Azacitidine-Teva to children (under 18 years).

You will have blood tests before you begin treatment with Azacitidine-Teva 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.

- If you are older than 65 years, your doctor will give you the regular blood tests described above but may also check your kidney function during your treatment with other tests.
- AZACITIDINE-TEVA can cause a serious immune reaction called 'differentiation syndrome' (see section 6 on Side Effects).

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-Teva.

4. How am I given Azacitidine-Teva?

How is Azacitidine-Teva given

- Azacitidine-Teva will be given to you as an injection under the skin (subcutaneously i.e. under the skin on your thigh, abdomen or upper arm) or as an intravenous infusion by a doctor or a nurse. Your doctor will choose the correct dose of azacitidine for you.

How much Azacitidine-Teva will be given

- Your 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-Teva per metre squared of body surface area.
- Initially, Azacitidine-Teva will be given daily for 7 days. 21 days later, you will have Azacitidine-Teva 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.
- Azacitidine-Teva 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-Teva.
- If you have any further questions on the use of Azacitidine-Teva, ask your doctor or pharmacist.

If you miss a dose of Azacitidine-Teva

It is very important for you to keep all appointments to receive Azacitidine-Teva. If you miss an appointment, ask your doctor when to schedule your next dose.

If you use too much Azacitidine-Teva

As Azacitidine-Teva is given to you under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given Azacitidine-Teva, tell your doctor immediately.

5. What should I know while receiving Azacitidine-Teva?

Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Azacitidine-Teva.
- 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.

Call your doctor straight away if you:

- stop passing urine or if you are passing less urine than normal.
- become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using Azacitidine-Teva.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Azacitidine-Teva affects you.

Looking after your medicine

Your doctor or pharmacist is responsible for storing Azacitidine-Teva. They are also responsible for disposing of any unused Azacitidine-Teva correctly.

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.

Serious side effects

Serious side effects	What to do
Allergic reaction: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue, or other	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
<p>parts of the body; rash; itching or hives on the skin</p> <p>Bleeding in the brain (a type of stroke): 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.</p> <p>Pneumonia (a serious lung infection): Fever; chills; shortness of breath; cough; phlegm; or occasionally coughing up blood.</p> <p>Sepsis (blood infection) or other frequent infections: 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.</p>	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Bleeding in your gut: Vomiting blood or material that looks like coffee grounds; bleeding from the back passage; black sticky bowel motions (stools); or bloody diarrhoea.</p> <p>Serious immune reaction (differentiation syndrome): Fever; cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain.</p> <p>Cutaneous vasculitis: Inflammation of blood vessels in the skin which may result in a rash. Azacitidine-Teva 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.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Bleeding in the eyes: Pain in one or both eyes, changes in vision.</p> <p>Blood in the urine</p> <p>Bleeding (including nose-bleeds) or bruising in the absence of injury, or you are more tired than usual.</p>	

Other side effects

Very 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 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Very common side effects	What to do
<ul style="list-style-type: none"> ● 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. 	

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. Some of these side effects (for example, high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

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.

What Azacitidine-Teva contains

Active ingredient (main ingredient)	Azacitidine
Other ingredients (inactive ingredients)	Sucrose Monobasic sodium phosphate monohydrate Dibasic sodium phosphate dihydrate

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

What Azacitidine-Teva looks like

Azacitidine-Teva is a white powder for suspension for injection and is supplied in a glass vial containing 100 mg of azacitidine.

Who distributes Azacitidine-Teva

Teva Pharma Australia Pty Ltd
Level 1, 37 Epping Road
Macquarie Park NSW 2113

Australian Registration Number: AUST R 299040

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