

AZACITIDINE ACCORD

Azacitidine Powder for Injection 100 mg/vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Azacitidine Accord.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Azacitidine Accord against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is Azacitidine Accord used for

Azacitidine Accord is an anti-cancer agent. Azacitidine Accord contains a medicine called azacitidine which prevents the growth of cancer cells. Azacitidine Accord 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 Accord works or why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you are given Azacitidine Accord

When you must not be given Azacitidine Accord

Tell your doctor:

- **If you are allergic to azacitidine or any of the other ingredients of Azacitidine Accord 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.
- **If you have advanced liver cancer.**
- **If you are pregnant.**
- **If you have severe problems with your kidney function.**

Before you are given Azacitidine Accord

1. Use by 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 three (3) 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.

2. Use by 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 (3) 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. Use by all patients

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

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

Before receiving Azacitidine Accord, tell your doctor if you have had any heart problems or lung disease.

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.

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.

Taking other medicines

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

How you will be given Azacitidine Accord

Azacitidine Accord 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 Accord for you.

- 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 Accord per metre squared of body surface area.
- 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.

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.

If you have any further questions on the use of Azacitidine Accord, ask your doctor or pharmacist.

While you are being treated with Azacitidine Accord

Things you must 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.

Things to be careful of

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Azacitidine Accord.

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- **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.**

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- **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 reaction.

- **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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you unwell.

Other side effects not listed above may also 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.

Product Description

What Azacitidine Accord looks like

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

Ingredients

- The active substance is azacitidine.
- The other ingredient is mannitol.

This medicine does not contain lactose.

Name and Address of the Sponsor

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

Australian Registration Number

100 mg: AUST R 265774

Date of preparation

This leaflet was prepared on 08 May 2017.

Storage

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