

# VIDAZA®

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## 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.

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### 1. Why am I given VIDAZA

VIDAZA contains the active ingredient azacitidine. VIDAZA 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 VIDAZA?](#) in the full CMI.

### 2. What should I know before I am given VIDAZA?

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 VIDAZA?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with VIDAZA 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 VIDAZA**

VIDAZA will be given to you in hospital or clinic under the supervision of an experienced doctor

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

### **5. What should I know while receiving VIDAZA**

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

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

## **6. Are there any side effects?**

Like all medicines, VIDAZA 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.

# VIDAZA®(vih-DAY-zuh)

**Active ingredient(s):** azacitidine (ay# za sye# ti deen)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using VIDAZA. **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 VIDAZA.**

**Where to find information in this leaflet:**

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

## 1. Why am I given VIDAZA?

**VIDAZA contains the active ingredient azacitidine.** VIDAZA is an anti-cancer agent. VIDAZA contains a medicine called azacitidine which prevents the growth of cancer cells.

**VIDAZA 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 VIDAZA works, or why this medicine has been prescribed for you.

VIDAZA 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 VIDAZA?**

### **Warnings**

#### **Do not use VIDAZA if:**

- you are allergic to azacitidine or any of the ingredients of VIDAZA 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 VIDAZA but if you do, tell your doctor immediately.

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

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

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

## **1. Use by men**

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

## **2. Use by all patients**

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

**Do not give VIDAZA to children (under 18 years).**

**You will have blood tests before you begin treatment with VIDAZA 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.
- VIDAZA 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 or have recently taken 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 VIDAZA.**

### **4. How am I given VIDAZA?**

#### **How is VIDAZA given**

- VIDAZA 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 VIDAZA for you.

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

## **If you miss a dose of VIDAZA**

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

## **If you use too much VIDAZA**

As VIDAZA 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 VIDAZA, tell your doctor immediately.

## **5. What should I know while receiving VIDAZA?**

### **Things you should do**

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

- 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 VIDAZA.

### **Driving or using machines**

**Be careful before driving or operating machinery until you know how VIDAZA affects you.**

### **Looking after your medicine**

Your doctor or pharmacist is responsible for storing VIDAZA. They are also responsible for disposing of any unused VIDAZA 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
<p>Allergic reaction</p> <ul style="list-style-type: none"><li>• 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</li></ul> <p>Bleeding in the brain (a type of stroke)</p> <ul style="list-style-type: none"><li>• A sudden severe headache; weakness or numbness in the face, arm, or leg; changes in vision; trouble speaking or understanding</li></ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>speech; or loss of coordination.</p> <p>Pneumonia (a serious lung infection)</p> <ul style="list-style-type: none"> <li>● Fever; chills; shortness of breath; cough; phlegm; or occasionally coughing up blood.</li> </ul> <p>Sepsis (blood infection) or other frequent infections</p> <ul style="list-style-type: none"> <li>● 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.</li> </ul> <p>Bleeding in your gut</p> <ul style="list-style-type: none"> <li>● Vomiting blood or material that looks like coffee grounds; bleeding from the back passage; black sticky bowel motions (stools); or bloody diarrhoea.</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="204 264 751 365">Serious immune reaction (differentiation syndrome)</p> <ul data-bbox="204 398 767 1120" style="list-style-type: none"> <li data-bbox="204 398 767 795">● Fever; cough, difficulty breathing, rash, decreased urine, low blood pressure (hypotension), swelling of the arms or legs and rapid weight gain.</li> <li data-bbox="204 840 767 1120">● Bleeding (including nose-bleeds) or bruising in the absence of injury, or you are more tired than usual.</li> </ul> <p data-bbox="204 1171 647 1216">Cutaneous vasculitis</p> <ul data-bbox="204 1249 778 1417" style="list-style-type: none"> <li data-bbox="204 1249 778 1417">● Inflammation of blood vessels in the skin which may result in rash.</li> </ul> <p data-bbox="237 1440 772 1951">VIDAZA 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>	

<b>Serious side effects</b>	<b>What to do</b>
Bleeding in eyes <ul style="list-style-type: none"> <li>● Pain in one or both eyes, changes in vision.</li> <li>● Blood in the urine.</li> </ul>	

## **Other side effects**

<b>Very common side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● sore throat or trouble swallowing; feeling of tension in the nose, cheeks or behind your eyes; runny or blocked nose.</li> <li>● Trouble sleeping ; feeling tired or lacking energy; dizziness; headache; anxiety; or feeling confused.</li> <li>● Loss of appetite, decreased weight, constipation, stomach pain, indigestion.</li> <li>● Cold sores or bleeding from the gums.</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

<b>Very common side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● 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.</li> <li>● Muscle or joint pain.</li> <li>● Chest pain.</li> </ul>	

**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](http://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 VIDAZA contains**

<b>Active ingredient (main ingredient)</b>	azacitidine
<b>Other ingredients (inactive ingredients)</b>	mannitol

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

### **What VIDAZA looks like**

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

(Aust R 153080).

### **Who distributes VIDAZA**

Bristol-Myers Squibb Australia Pty Ltd



4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: [MedInfo.Australia@bms.com](mailto:MedInfo.Australia@bms.com)

VIDAZA® is a trademark of Celgene Corporation, a Bristol Myers Squibb Company.

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