

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrVIDAZA®**

#### **azacitidine for injection**

Read this carefully before you start taking **VIDAZA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VIDAZA®**.

#### **Serious Warnings and Precautions**

**VIDAZA®** should be prescribed and managed only by a doctor experienced in the use of anticancer drugs.

**VIDAZA®** can cause serious side effects including:

- thrombocytopenia (abnormally small number of platelets in the blood);
- kidney failure. This is rare, but can be life-threatening.
- differentiation syndrome (rapid release of immune cells from cancer cells).

#### **What is **VIDAZA®** used for?**

**VIDAZA®** is used to treat adults with either myelodysplastic syndrome (MDS) or Acute Myeloid Leukemia (AML). These patients will not be able to have a stem cell transplant.

#### **How does **VIDAZA®** work?**

**VIDAZA®** works by helping to make healthy cells in the bone marrow. It may also kill cells in bone marrow that have been reproducing abnormally.

#### **What are the ingredients in **VIDAZA®**?**

Medicinal ingredients: azacitidine

Non-medicinal ingredients: mannitol

#### **VIDAZA® comes in the following dosage forms:**

Powder: 100 mg

#### **Do not use **VIDAZA®** if:**

- you are allergic to azacitidine or to any of the other ingredients of **VIDAZA®**
- you have advanced liver cancer

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take **VIDAZA®**. Talk about any health conditions or problems you may have, including if you:**

- have low blood platelets
- have kidney disease

- have liver disease
- have congestive heart failure or heart disease
- are over 65 years of age

**Other warnings you should know about:**

While receiving VIDAZA<sup>®</sup>, you may need supportive care.

Treatment with VIDAZA<sup>®</sup>, may cause:

- **Differentiation syndrome.** This is a serious and life-threatening condition. If you experience trouble breathing, chest pain, cough, fever, rash, swelling, rapid weight gain, low blood pressure and light headedness, contact your healthcare professional right away. You may be experiencing differentiation syndrome. Your VIDAZA<sup>®</sup>, may need to be stopped and you may need treatment with other medicines called corticosteroids.
- **Low blood counts** including **thrombocytopenia, anemia** (low red blood cells) and **neutropenia** (low white blood cells).
  - Your healthcare professional will do blood tests before you start treatment. These tests will be repeated before each treatment cycle. Your healthcare professional will also watch you for signs of bleeding. You may need blood transfusions.
  - Tell your healthcare professional right away if you experience a fever. Having a low white blood cell count can make you more likely to get an infection.

Treatment with VIDAZA<sup>®</sup> may increase your risk for other cancers in the future.

**Female patients – pregnancy and breastfeeding:**

- If you are pregnant or are planning to get pregnant and / or breastfeed, there are specific risks you should discuss with your healthcare professional.
- You should not get pregnant while you are receiving VIDAZA<sup>®</sup>. It may harm your unborn baby.
- If you are able to get pregnant, you must use an effective method of birth control during treatment. Continue to use this birth control for at least 6 months after stopping your treatment with VIDAZA<sup>®</sup>.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant while you are receiving VIDAZA<sup>®</sup>.
- Do not breastfeed while are you are receiving VIDAZA<sup>®</sup>.

**Male patients - pregnancy:**

- You should not father a child while receiving VIDAZA<sup>®</sup> and for 6 months after your last dose.
- If you have a female sexual partner, she should not get pregnant while you are receiving VIDAZA<sup>®</sup>.
- If, during your treatment with VIDAZA<sup>®</sup>, your sexual partner becomes pregnant or thinks she may be pregnant, tell your healthcare professional right away.

VIDAZA<sup>®</sup> is not recommended for use in children and adolescents below the age of 18.

**Driving and using machines:** VIDAZA<sup>®</sup> may cause fatigue. Before you do tasks that may require special attention, wait until you know how you respond to VIDAZA<sup>®</sup>. If you feel tired, do not drive or use machines or tools.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with VIDAZA<sup>®</sup>:**

- There are no known drug interactions with VIDAZA<sup>®</sup>.

**How to take VIDAZA<sup>®</sup>:**

- Vidaza<sup>®</sup> will be given to you by a healthcare professional. It will first be mixed with sterile water to form a suspension. This suspension is then injected subcutaneously. This means it is injected under your skin.
- Before receiving Vidaza<sup>®</sup>, your healthcare professional will give you another medicine to prevent nausea and vomiting.
- You will receive VIDAZA<sup>®</sup> every day for 7 days in a row. This is followed by a rest period of 21 days (3 weeks). One week of treatment and a 3-week rest period is considered a “treatment cycle”. You may receive 6 or more cycles of treatment.

**Usual dose:**

- The adult usual dose is 75 mg / m<sup>2</sup>. This means that the amount of VIDAZA<sup>®</sup> you receive will depend on your height and weight.
- Your healthcare professional may change your dose, stop your treatment for a short time or stop it completely. This may happen if you experience certain side effects. Your doctor will check your progress and may change your dose if necessary.

**Overdose:**

If you think you, or a person you are caring for, have been given too much VIDAZA<sup>®</sup>, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you think that you have missed a dose of VIDAZA<sup>®</sup>, tell your healthcare provider immediately.

## What are possible side effects from using VIDAZA®?

These are not all the possible side effects you may have when taking VIDAZA®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects are usually more common during the first 2 cycles of treatment. They may be less common with further treatment.

- Constipation, diarrhea, nausea, vomiting
- Loss of appetite
- Pain in your belly
- Indigestion
- Sores in your mouth or on your tongue
- Weight loss
- Fever
- Sore nose and throat
- Pain in your throat and voice box
- Infection of the nose and throat, or sore throat; sore or runny nose or sinuses
- Chest pain
- Being short of breath, may happen when you move
- Feeling tired
- Lethargy
- Feeling generally unwell
- Bruising, redness, rash, itching, swelling, hard lump, change in the colour of the skin, pain or a skin reaction at the location where the needle enters your skin during injection
- Bruising, rash, red or purple spots under your skin
- Itching
- Hair loss
- Joint and muscle aches
- Dizziness
- Headache
- Anxiety
- Being confused
- Trouble sleeping
- Cold sores (a viral infection)
- High or low blood pressure

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Infection:</b> fever and chills, nausea, vomiting, diarrhea, generally feeling unwell		✓	
<b>Blood problems including:</b> <b>Anemia</b> (low red blood cells): fatigue, loss of energy, pale, chest pain, shortness of breath, palpitations, weakness <b>Neutropenia</b> (low white blood cells): infections, fatigue, fever, aches, pains, flu-like symptoms <b>Thrombocytopenia</b> (low blood platelets): unexpected bruises of any size, bleeding for longer than usual if you hurt yourself, pale, fatigue, weakness		✓	
<b>COMMON</b>			
<b>Pneumonia</b> (infection in the lungs): coughing, fever, shortness of breath, chest pain		✓	
<b>Urinary tract infection:</b> Frequent need to urinate, pain or burning when you urinate, urine cloudy or smells bad, fever, chills	✓		
<b>Sepsis</b> (infection of the blood): fever or dizziness, chills, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat		✓	

<p><b>Hypokalemia</b> (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling or numbness</p>		✓	
<p><b>Hemorrhage</b> (bleeding from different sites including GI tract, brain, eye and skin): vomiting up blood, black and tarry stool, bleeding from the rectum, abdominal pain, bleeding from gums or mouth, bleeding from hemorrhoids, seizures, loss of consciousness, severe headache, nosebleed, red patch on the white part of the eye, bruising or tiny red dots on the skin, blood in urine</p>			✓
<b>UNCOMMON</b>			
<p><b>Allergic reaction:</b> difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, itching, hives or rash, swelling of the face, lips, tongue or throat</p>			✓
<b>VERY RARE</b>			
<p><b>Tumor lysis syndrome</b> (the sudden, rapid death of cancer cells due to the treatment): nausea, shortness of breath, irregular heartbeat, lack of urination, cloudy urine, muscle spasms or twitching, muscle weakness, tiredness, joint pain</p>		✓	
<p><b>Injection site necrosis</b> (death of cells and tissue at the injection site): dark brown or black skin, redness, swelling, pain, change in skin colour, ulcers, blisters or black spots on the skin, fatigue, dizziness</p>		✓	

<b>Necrotizing fasciitis</b> (a severe, life-threatening bacterial infection of the skin and soft tissue): skin that is red, warm, swollen or very painful, ulcers, blisters, black spots on the skin, changes in skin colour, fatigue, dizziness			✓
<b>Pyoderma gangrenosum</b> (a rare skin condition): large painful skin ulcers usually on the legs		✓	
<b>Hepatic coma</b> (unconsciousness from severe liver problems): drowsiness, shaking, yellow skin and eyes (jaundice), abdominal bloating, easy bruising			✓
<b>Kidney failure:</b> swelling of the legs and feet, back pain, reduced passing of water, increased thirst, rapid pulse, dizziness and nausea, vomiting or reduced appetite, feelings of confusion, restlessness or fatigue			✓
<b>Differentiation syndrome</b> (rapid release of immune cells from cancer cells): trouble breathing, chest pain, cough, fever, rash, swelling, rapid weight gain, low blood pressure, light headedness			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store at room temperature (15 to 30°C).

Keep out of reach and sight of children.

### **If you want more information about VIDAZA®:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://bms.com/ca/en>, or by calling 1-866-463-6267.

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