PART III: CONSUMER INFORMATION

Pr VIDAZA®

azacitidine for injection

This leaflet is part III of a three-part "Product Monograph" published when VIDAZA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VIDAZA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

VIDAZA® is used in adults with either myelodysplastic syndrome (MDS) or Acute Myeloid Leukemia (AML) who are not eligible for stem cell transplantation. Both MDS and AML are blood disorders.

- In MDS, the bone marrow does not function and fails to produce enough healthy blood cells. You will only be given VIDAZA® if your form of MDS is considered "higher risk". Higher risk means that there is a danger that the disease will be fatal or that the patient could develop AML.
- AML is a type of cancer affecting the bone marrow, where blood cells develop. Blood cells that are not fully formed and do not work well are found in the blood.

What it does:

In patients with MDS and AML, VIDAZA® works by helping to correct the problem with the growth of immature cells in the bone marrow. VIDAZA® may also kill cells in bone marrow that have been reproducing abnormally.

When it should not be used:

Do not use VIDAZA®:

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

What the medicinal ingredient is:

azacitidine

What the important nonmedicinal ingredients are:

Mannitol

What dosage forms it comes in:

VIDAZA® is supplied as a sterile freeze dried powder. After it is mixed with sterile water, it forms a suspension that can be injected subcutaneously (under the skin). Each vial contains 100 mg of azacitidine.

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:

- thrombocytopenia (abnormally small number of platelets in the blood);
- in rare cases, kidney failure, which can be life-threatening.

While taking VIDAZA®, you may receive supportive care to protect you from serious bleeding, anemia, infection, nausea and vomiting.

BEFORE you use VIDAZA® talk to your doctor or pharmacist if you:

- have low blood cell count (platelets, red or white blood cells)
- have kidney disease
- have liver disease
- have congestive heart failure
- are breastfeeding, pregnant or are planning to get pregnant

VIDAZA® may cause harm to an unborn baby. Females who could become pregnant should use effective contraception during treatment and up to 3 months after stopping treatment with VIDAZA®. Male patients should not father a child while receiving treatment with VIDAZA® and for 6 months after the last dose.

VIDAZA® may cause tumor lysis syndrome (metabolic abnormalities caused by the death of tumor cells), injection site necrosis (a serious condition due to the death of cells and tissue at the injection site), necrotizing fasciitis (a severe, life-threatening bacterial infection of the skin and soft tissue) and pyoderma gangrenosum (painful skin ulceration).

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

INTERACTIONS WITH THIS MEDICATION

Interaction with other drugs is not known. You should tell your doctor or pharmacist about your other medicines including any that you bought without a prescription. These include vitamins and herbal products. While taking VIDAZA®, you should check with your doctor or pharmacist before taking any other medicines.

PROPER USE OF THIS MEDICATION

Your doctor will give you another medicine to prevent nausea and vomiting.

- Your doctor will choose your dose of VIDAZA® depending on your general condition, height and weight.
- VIDAZA® is given to you as an injection under the skin (subcutaneously) by a doctor or nurse. It may be given under the skin on your thigh, stomach or upper arm.

Usual dose:

- The usual dose is 75 mg per square meter of your body surface area.
- Your doctor will check your progress and may change your dose if necessary.
- VIDAZA® is given every day for 7 days in a row, followed by a rest period of 3 weeks. This "treatment cycle" will be repeated every 4 weeks. The treatment usually consists of at least 6 cycles.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you think that you have been given VIDAZA® more frequently than you should, or too high a dose, tell your healthcare provider immediately or contact your local poison control centre immediately.

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, VIDAZA® can cause side effects. Side effects are usually more common during the first 2 cycles of treatment. They may be less common with further treatment.

Tell your doctor right away if you notice any of the following side effects:

- Fever - This may be due to an infection due to having a low white blood cell count.
- Chest pain or shortness of breath with or without fever - This may be due to an infection in your lungs called "pneumonia".
- Unexpected bleeding.
- Difficulty breathing, swelling of the lips, itching, or rash, which may be due to an allergic reaction.

Very common: Reduced red and/or white blood count; reduced platelet count; constipation; diarrhea; nausea; vomiting; pneumonia; chest pain; being short of breath; feeling tired; redness, pain or a skin reaction at the location where the needle enters your skin during injection; loss of appetite; joint aches; bruising; rash; red or purple spots under your skin; pain in your belly; itching; fever; sore nose and throat; dizziness; headache

Common: Bleeding inside your brain; blood infection; bone marrow failure leading to low red or white blood cell counts, or a low platelet count; low red and white blood cell counts, with a low platelet count occurring at the same time; urinary infection; cold sores (a viral infection); bleeding gums; bleeding in the stomach or gut; bleeding from hemorrhoids; bleeding in your eye; bleeding under your skin, or into your skin; blood in your urine; ulcers of your mouth or tongue; side effects where the needle went into your skin, including swelling, a hard lump, bruising, bleeding into your skin, rash, itching and/or changes in the color of the skin; redness of your skin; infection of the nose and throat, or sore throat; sore or runny nose or sinuses, low levels of potassium in your blood; high or low blood pressure; shortness of breath when you move; pain in your throat and voice box; indigestion; weight loss; lethargy; feeling generally unwell; muscle aches; anxiety or having trouble sleeping; being confused, hair loss

Uncommon: Allergic reaction

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Common	Fever / Infection or fever with low neutrophil count		✓	
Common	Feeling weak or tired with or without fever, unexpected bruises of any size, looking pale, chest pain, shortness of breath, palpitations / Blood system disorders		✓	
Common	Coughing, fever, with shortness of breath / Pneumonia		✓	
Common	Frequent need to urinate, pain or burning when you urinate, urine cloudy or smells bad, fever, chills / Urinary tract infection	✓		
Common	Nosebleed, bleeding from the eye or mouth	✓		
Common	Seizures, loss of consciousness, severe headache / Bleeding in the brain		✓	
Common	Blood in stool and urine		✓	
Uncommon	Allergic reaction		✓	

This is not a complete list of side effects. For any unexpected effects while taking VIDAZA®, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15 to 30°C). Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The information in this document is current as of the last revision date shown below. The most current information can be found at: http://www.celgenecanada.net or by contacting the sponsor, Celgene Inc., at:
1-888-712-2353 extension 4850

This leaflet was prepared by Celgene Inc.

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