Azacitidine Oral Formulation (Onureg®)

**Pronounced:** ay-za-SYE-ti-deen

**Classification:** DNA Demethylating Agent

**About Azacitidine Oral Formulation (Onureg®)**

Azacitidine kills abnormal cells in the bone marrow by inhibiting a process called DNA methylation, which is essential for cell reproduction. Because the abnormal cells cannot divide and grow, they die.

**How to Take Azacitidine (Onureg®)**

Azacitidine comes as a tablet to take by mouth. Do not split, crush, or chew azacitidine tablets. Take a dose about the same time each day, with or without food. If a dose of azacitidine is missed or not taken at the usual time, take the dose as soon as possible on the same day, and resume the normal schedule the following day. Do not take 2 doses on the same day. If a dose is vomited, do not take another dose on the same day. Resume the normal schedule the following day.

Your provider may prescribe medication to prevent nausea and vomiting (an antiemetic) while taking azacitidine. You should take this medication 30 minutes before each dose of azacitidine.

You may need to have your blood levels checked before taking this medication. Your provider will discuss these results with you and if you should change how you take azacitidine.

**Storage and Handling**

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). Do not remove the 2 desiccant containers that are inside the original bottle.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. If the powder from the tablets comes in contact with your or your caregiver’s skin, wash the area well right away with soap and water. If the powder from the tablets comes in contact with your or your caregiver’s eyes or mouth, flush the area right away with water. Pregnant or nursing women should not prepare the dose for you.

Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

**Where do I get this medication?**

Azacitidine is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

**Insurance Information**

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources if they are available.
If you have Medicare, it is important to know that some cancer medications that are available in both IV and oral forms are covered differently under Medicare. Talk with your pharmacist about if this drug is a Part B or Part D (prescription) covered drug so that it is processed correctly based on your coverage.

**Possible Side Effects**

There are a number of things you can do to manage the side effects of azacitidine. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Diarrhea**

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)**

This medication can cause life-threatening infections, including pneumonia, with or without a decrease in white blood cell counts.

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

**Tips to prevent infection:**

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e., those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Constipation**
There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Abdominal (Belly) Pain**

This medication can cause belly pain, with or without diarrhea. Tell your provider if you have belly pain.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib), etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding the use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**Less common, but important side effects can include:**

- **Increased Early Mortality in Patients with Myelodysplastic Syndromes:** In patients with MDS, there was a higher chance of severe infections and death when treated with azacitidine.

**Sexual & Reproductive Concerns**

This medication may affect your ability to have children. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control for women is necessary during treatment and for at least 6 months after treatment. For men, effective birth control should be used during treatment and for 3 months after treatment ends. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication or for 1 week after your last dose.