

ORAL CHEMOTHERAPY EDUCATION



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AZACITIDINE

Name of your medication

Generic name — azacitidine (ay-zuh-SY-tih-deen)

Brand name — ONUREG® (on-u-reg)

Approved uses

Azacitidine is used in the treatment of adults with acute myeloid leukemia.

Dose and schedule

Taking azacitidine as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of azacitidine is 300 mg orally once daily on days 1 through 14 of each 28-day cycle.
- Your dose is based on many factors, including your overall health and diagnosis.
- Administer an antiemetic 30 minutes before each dose, for at least the first 2 cycles.
- Azacitidine can be taken with or without food, but should be taken at the same time each day.
- Azacitidine should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow azacitidine, talk to your care provider or pharmacist for possible options.
- Do not substitute oral azacitidine for intravenous or subcutaneous azacitidine.
- If you miss a dose of azacitidine:
 - If a dose 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.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.
- Do not take an additional dose if vomiting occurs after taking azacitidine. Instead, continue with your next scheduled dose the following day.

Drug and food interactions

- Azacitidine has potential drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

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Storage and handling

Handle azacitidine with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store azacitidine at room temperature (68°F–77°F) in a dry location away from light.
- Leave azacitidine in the provided packaging until it is ready to be taken.
- Keep bottle tightly closed. Store and dispense in the original bottle (with 2 desiccant canisters). Do not swallow the desiccants.
- Keep azacitidine out of reach of children and pets.
- Whenever possible, you should give azacitidine to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the azacitidine to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the azacitidine from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is not recommended to be used with azacitidine.
- If you have any unused azacitidine, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of azacitidine.
- If you are traveling, put your azacitidine in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.
 3. Gently transfer the azacitidine from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.

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Side Effects of Azacitidine

Below are common side effects that have been known to happen in about one-third or more of patients taking azacitidine; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake because of some other health problem. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains). • Avoid foods that cause gas (e.g., broccoli, beans). • Avoid lactose-containing foods (e.g., yogurt, milk). • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>

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Possible Side Effect	Management
Constipation	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Stay active and exercise, if possible. • Eat foods high in fiber, like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in 3 or more days.</p> <p>Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener, such as docusate (Colace®), and/or a laxative, such as senna (Senokot®), may be helpful. If these do not help within 48 hours, tell your provider.</p>
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is OK to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
Decreased white blood cells (WBCs) and increased risk for infection	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>

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Possible Side Effect	Management
Decreased platelet count and increased risk of bleeding	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none">• Use caution to avoid bruises, cuts, or burns.• Blow your nose gently, and do not pick your nose.• Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene.• When shaving, use an electronic razor instead of razor blades.• Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include the following:</p> <ul style="list-style-type: none">• A bloody nose that bleeds for more than 5 minutes despite pressure• A cut that continues to ooze despite pressure• Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

Serious side effects

- Azacitidine may cause rare but serious side effects, including the following:
 - Fertility problems in men and women.
 - Birth defects: Do not take azacitidine if you are pregnant or think you might be pregnant.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since azacitidine remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take azacitidine, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.

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- If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
- Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or azacitidine with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking azacitidine.
- Advise men of reproductive potential to use effective contraception during treatment with azacitidine and for at least 3 months after the last dose.
- Advise women of reproductive potential to use effective contraception during treatment with azacitidine and for at least 6 months after the last dose.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods.
- There are no data regarding the presence of azacitidine in human milk or its effects on the breastfed child or milk production.
- Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with azacitidine and for 1 week after the last dose.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- Talk with your care provider about the process for obtaining your azacitidine.

(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website:

https://www.onuregpro.com/?gclid=EAlaIQobChMI2sL1iaHa6wIVUvDACH3hvw51EAAYASAAEglyDPD_BwE,
https://packageinserts.bms.com/ppi/ppi_onureg.pdf

Product prescribing information:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/214120s000lbl.pdf

Product resources: <https://www.bmsaccesssupport.bmscustomerconnect.com/patient>

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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