

# A guide for getting started with ONUREG®

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for ONUREG®.





Getting your acute myeloid leukemia (or AML) into remission can be a difficult journey. Now that you're here, you may feel confused or uncertain about what happens next. You may also have questions about starting **ONUREG**<sup>®</sup>. All your concerns and feelings are normal.

Throughout this guide, you'll learn about ONUREG, an oral medication that you can take at home or anywhere that is convenient.

ONUREG may help you **live longer\*** so you can focus on the everyday moments that are most important to you.

Ask your healthcare team about **AML treatment** recommendations from the National Comprehensive Cancer Network® (NCCN®)<sup>†</sup>

Your support system is important. **Share this brochure** with friends or loved ones to learn about ONUREG together.

\*In a clinical trial, people with AML who took ONUREG lived longer overall than people who took placebo (an inactive medicine). Median overall survival was 24.7 months with ONUREG vs 14.8 months with placebo. Learn more about the trial on page 6 of this brochure.

<sup>†</sup>Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 26, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

### What is ONUREG?

ONUREG (azacitidine) is an oral prescription medicine used to treat adults with acute myeloid leukemia (AML) who:

Are in first **c**omplete **r**emission (**CR**) (with or without recovery of your blood cell counts) after intensive induction chemotherapy **and** are not able to complete intensive curative therapy.

It is not known if ONUREG is safe and effective in children under 18 years of age.

# In this guide you'll find helpful information and tips as you begin your ONUREG journey

## **Understand AML remission** What is AML remission and why is it important? Learn about the potential benefits of ONUREG Why ONUREG? **Learn about possible ONUREG side effects** What are the potential side effects of ONUREG? How are ONUREG side effects managed? **Understand how to take ONUREG** How should I take ONUREG? Find resources and support What are some frequently asked questions about ONUREG? Is financial support available for ONUREG? Where can I go for more resources and support? What are the most common words used with AML?

Do not take ONUREG if you are allergic to azacitidine or any of the ingredients in ONUREG.





**Review important facts about ONUREG** 

# What is AML remission and why is it important?

# Remission is a sign that your AML is under control

## What is acute myeloid leukemia (AML)?

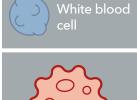
AML is a type of leukemia or blood cancer. 'Acute' means that AML usually gets worse quickly if it is not treated.



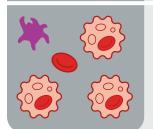
Blood cells are made in your bone marrow by different 'families' of blood stem cells. One family, called the 'myeloid' family, develops:



- Platelets, which help with blood clotting
- Red blood cells, which transport oxygen
- White blood cells, which help fight infection



In AML, myeloid blood cells don't form properly. Instead, immature abnormal cells (or **blasts**) are produced.



Blast

Blasts create chaos in your bone marrow by growing, multiplying, and crowding out normal healthy cells.

This is what causes the symptoms of AML.

### What is AML remission?

**Remission** means that less than 5% of your bone marrow contains blasts (immature abnormal cells).

 Number of blasts is typically measured by a bone marrow biopsy

Remission isn't the same for everyone:

- Complete remission (or CR) means you have less than 5% blasts, and all your blood counts are normal
- Complete remission with incomplete blood count recovery (or CRi) means you have less than 5% blasts, but some of your blood counts have still not returned to normal

Remission doesn't mean you're cured.

Click here to visit <a href="https://know-aml.com/understanding-aml">https://know-aml.com/understanding-aml</a> to learn more about AML and remission

# **Treating AML after remission is important\***

- When you're in remission there are no visible signs of disease, but some cancer cells may be left behind
- When those cells grow, your AML can return, causing a relapse



## **Continued treatment**

- A long-term treatment for people who are in remission
- The goal of continued treatment is to kill cancer cells that may be left behind

# Remission



After remission, each person's journey is different.

- Some (but not all) people receive additional chemotherapy called consolidation therapy
- People planning to get a transplant may wait several months



# **Transplant**

- An intense procedure that replaces unhealthy stem cells with healthy cells
- The goal of transplant is to potentially cure AML
- Some people receive additional treatment after transplant

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for ONUREG®.



<sup>\*</sup>Some people are watched closely after remission, but not treated until their AML comes back. Doctors call this 'active surveillance' or 'watch and wait'.



# ONUREG is an oral medication that was studied in a large clinical trial

- ONUREG was tested against placebo, an inactive medicine
- 238 people were treated with ONUREG and 234 people were treated with placebo
- People in the trial were between 55 and 86 years old
- Everyone was in first remission following intensive induction chemotherapy with or without consolidation therapy
- The trial only included people who were not planning to receive a transplant



**Overall survival** is an important data point that is one way to show how well a treatment works in a clinical trial.

- It represents the length of time that a person lives after starting a medication
- When an AML medication achieves longer overall survival, it offers people the chance for more life



In the ONUREG clinical trial, **median overall** survival was used to compare:

 The length of time when 50% (or half) the people treated with ONUREG were still alive

#### VS

 The length of time when 50% (or half) the people treated with placebo were still alive

# Before taking ONUREG, what should I discuss with my healthcare team?



Talk to your healthcare team about all of your medical conditions, including if you have kidney or liver problems.

AML REMISSION WHY ONUREG? SUPPORT SIDE EFFECTS TAKING ONUREG SUPPORT

# ONUREG helped patients like you live longer

# People treated with ONUREG had longer median overall survival

Half the people in the trial were still alive at:

## 2 YEARS

(25 months) with ONUREG

VS

## **1.25 YEARS**

(15 months) with placebo

# Additional results\* from the study showed:



~Three out of four (73%) people who received ONUREG were alive at one year



~Two out of four (56%) people who received placebo were alive at one year

\*Important to know: Estimated overall survival results should be viewed with caution. The ONUREG trial was designed to compare median overall survival with ONUREG vs placebo. It was not designed to compare survival at other time points.

These outcomes were experienced by people in the ONUREG clinical trial. Your results may vary.



Talk to your healthcare team about all the medicines you are taking, including:

Prescription medicines
 Over-the-counter medicines

Vitamins

Herbal supplements

These are not all the topics you should discuss with your healthcare team. Talk to your healthcare team about anything you might be unsure of before starting treatment.



# What are the potential side effects of ONUREG®?

It's natural to have questions about side effects when starting a new treatment.

And it's important to be aware of what side effects you may experience with ONUREG.

## The most common potential side effects of ONUREG include:

- Nausea and vomiting
- Diarrhea
- Feeling tired or weak
- Constipation
- Pain in the stomach (abdominal) area

- Pneumonia (lung infection)
- Joint pain
- Decreased appetite
- Pain in arms or legs
- Feeling dizzy

Most of the side effects people experienced in the ONUREG clinical trial were **mild or moderate**.

- These are not all the possible side effects of ONUREG
- If you experience any side effect of any severity, let your healthcare team know
- Some patients in the clinical trial experienced severe or serious side effects. See page 9 of this brochure
- Learn how you can help to manage side effects on page 11 of this brochure

Rely on your healthcare team.

They know what to look for and how to manage potential ONUREG side effects.

## **ONUREG** can cause serious side effects, including:

- Low white blood cell counts (also known as neutropenia) can be severe and put you at risk for infections that can be life-threatening
  - Your healthcare team will check your white blood cell counts before and during treatment with ONUREG
  - Your healthcare provider may prescribe a medicine to help increase your white blood cell count if needed
  - Your healthcare provider may prescribe antibiotics or anti-viral medications to help prevent infections
- Low platelet counts (also known as thrombocytopenia)
   can be severe and put you at risk for bleeding
  - Your healthcare team will check your platelet counts before and during treatment with ONUREG



# Tell your healthcare team right away if you experience:

- Fever or chills
- Body aches
- Feeling very tired or weak
- Headaches that are different from what you are used to
- Confusion



Tell your healthcare team right away if you have any unusual bruising or bleeding

These are not all the possible side effects of ONUREG. Talk to your healthcare team for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.



# How are ONUREG® side effects managed?

# Steps your healthcare team can take to help prevent and manage some ONUREG side effects

# Managing nausea, vomiting, or diarrhea

Your healthcare provider should prescribe an **anti-nausea medicine** 

- If you do not have an anti-nausea medicine, ask your doctor for a prescription to help prevent nausea/vomiting
- Take the medicine 30 minutes before each ONUREG dose for at least the first 2 months of treatment\*

If you take the anti-nausea medicine before each ONUREG dose but still experience nausea/vomiting, ask your healthcare team if **additional medicine** can help

If you experience **diarrhea or other side effects**, your doctor may prescribe medicine to help



# Monitoring blood counts

Your healthcare team will check your **blood counts** frequently<sup>†</sup>

- Every other week for the first two cycles (2 months)
- Prior to the start of each cycle after that
- Monitoring may increase to every other week if you experience certain side effects

# Dose changes<sup>‡</sup> to help manage side effects



If you develop certain side effects, your healthcare team may ask you to:

- Pause treatment temporarily
- Decrease the dose
- Decrease the number of treatment days

If your side effects persist after making these adjustments, your healthcare team may ask you to **permanently stop** taking ONUREG

Always tell your healthcare team if you experience any side effect with ONUREG.

Always remember that side effects are common. It is not your fault if your healthcare provider makes changes to your treatment.

<sup>\*</sup>After 2 months, ask your doctor if you should continue taking an anti-nausea medicine.

<sup>†</sup>If your blood count is low, your healthcare provider may recommend a prescription medicine or (if necessary) a blood transfusion.

<sup>&</sup>lt;sup>‡</sup>Do not reduce or discontinue medicine unless told to do so by your healthcare team.

# **Steps you can take at home** to help manage common ONUREG side effects

Consult your healthcare team before making any changes to your diet, physical activity, or treatment plan.

Common side effects		Ways to manage
	Nausea, vomiting	<ul> <li>Take an anti-nausea medicine 30 minutes before each dose of ONUREG</li> <li>Ask your healthcare team about taking extra medicine for nausea if it occurs</li> <li>Eat snacks or small meals during the day to keep something in your stomach</li> <li>Avoid greasy, fried, sweet, or spicy foods</li> </ul>
	Diarrhea	<ul> <li>Ask your healthcare team if you should take a medicine for diarrhea</li> <li>Keep a journal of your diet and your bowel movements to share with your healthcare team</li> <li>Drink plenty of fluids every day</li> <li>Eat small meals that are easy on your stomach</li> </ul>
\$ \$\$	Constipation	<ul> <li>Talk to your healthcare team about other medicines you may be taking (including anti-nausea medicines) that may cause constipation</li> <li>Ask your team if you should take a medicine or a stool softener for constipation</li> <li>Eat high-fiber foods</li> <li>Drink plenty of fluids</li> <li>Try to be active</li> </ul>
$\bigcap_{\mathbf{x}}$	Decreased appetite	<ul><li>Drink plenty of fluids</li><li>Eat small, healthy, high-nutrient meals</li></ul>
M	Feeling tired or weak	<ul> <li>Plan time to rest, and choose activities that are relaxing</li> <li>Ask your healthcare team if light exercise is advised</li> <li>Ask your healthcare team about liquid nutritional supplements</li> </ul>
****	Feeling dizzy	<ul><li>Walk slowly and carefully</li><li>Change positions slowly and sit up carefully after lying down</li></ul>
<b>Š</b>	Pain in stomach, joints, or arms/legs	<ul> <li>Discuss your pain with your healthcare team</li> <li>Ask if there are over-the-counter pain medicines that might help</li> </ul>



# How should I take ONUREG®?



Take ONUREG exactly as instructed by your healthcare team: once-daily for 14 days of every 28-day treatment cycle



Throughout treatment, your healthcare team may adjust your dose to help manage adverse reactions. Always take ONUREG exactly as directed.



Take an anti-nausea medicine 30 minutes before each dose of ONUREG



If you miss a dose or do not take ONUREG at the usual time

- Take the dose as soon as possible on the same day
- Resume the normal schedule the following day
- Do not take 2 doses on the same day to make up for a missed dose



Take doses at about the same time each day (with or without food) as part of your daily routine



If a dose is vomited, do not take another dose on the same day

• Resume the normal schedule the following day



Swallow ONUREG tablets whole. Do not cut, crush, or chew tablets\*



ONUREG is supplied in blister cards

- Each blister card contains 7 tablets
- You will receive 2 blister cards for each treatment cycle

<sup>\*</sup>If the powder from ONUREG tablets comes in contact with your skin, wash the area well right away with soap and water. If the powder from ONUREG tablets comes in contact with your eyes or mouth (mucous membranes), flush the area right away with water.



# What are some frequently asked questions about ONUREG®?

Whether you were just prescribed ONUREG or have already started treatment, here are some questions you may have.

### How do I get ONUREG?

Once prescribed, ONUREG is delivered to most patients by a specialty pharmacy.

• Specialty pharmacies handle medications, like ONUREG, that often aren't stocked at regular neighborhood pharmacies

### How long will I need to take ONUREG?

ONUREG may help you live longer after first remission. ONUREG is intended to be used until the AML comes back (also called a relapse) or until side effects cannot be managed. Talk to your healthcare team about your specific plan.

## How often should I come in for follow-up visits or blood work while taking ONUREG?

For the first two ONUREG cycles (first 2 months), your healthcare team will monitor your blood counts every other week. After the first two cycles, your blood counts will be checked prior to the start of every cycle (every month).

- Monitoring may increase to every other week if you experience certain side effects
- You may need to stop treatment (either temporarily or permanently) if you develop certain side effects

#### I have to travel a long distance to get to my doctor. Are there other options?

ONUREG is an oral medication that can be taken at home, but you will need to visit your healthcare team for follow-up visits and blood work. If you live a far distance away, ask your doctor if there are alternative options such as telemedicine for some appointments.

# How will ONUREG affect my daily life? Will I be able to do the things I enjoy (e.g., gardening, walking, golf, spending quality time with my family, traveling, etc.)?

Ask your healthcare team about the quality of your life and what to expect with ONUREG. Together you can come up with a plan that may help you do the things you enjoy while continuing treatment with ONUREG.

Throughout your ONUREG treatment journey, stay in close contact with your healthcare team.

They are your best source of information and guidance.

AML REMISSION WHY ONUREG? SIDE EFFECTS TAKING ONUREG SUPPORT

# Is financial support available for ONUREG?

Patient access, reimbursement, and co-pay support is available through:



Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer BMS Access Support. BMS Access Support provides resources to help patients understand their insurance coverage. In addition, we can share information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

#### For more information:



- Ask your doctor
- Visit <u>www.BMSAccessSupport.com</u>
- Call Bristol Myers Squibb Access Support at 1-800-861-0048,
   8 AM to 8 PM ET, Monday-Friday



# Where can I go for more resources and support?

Learn more about AML, connect with others, and get information and support from these respected organizations.



Information, patient-to-patient community support, and **personal health coaches** for people with AML

www.healthtree.org/aml



Education and support for blood cancer patients and families navigating cancer treatment

www.lls.org/leukemia/acute-myeloid-leukemia



Global education and awareness on AML including educational videos and animations

www.know-aml.com



Patient and caregiver resources, support groups, patient stories, and more

www.mds-foundation.org/what-is-aml

### **SHARE TO INSPIRE**

Because your story can help inspire another

Visit <u>www.sharetoinspire.com</u> to learn more

# What are the most common words used with AML?

The following list of words and phrases appear throughout this guide. Refer to this list if you are reading about AML online or when talking to your healthcare team.

**Acute myeloid leukemia:** A type of leukemia (or blood cancer) that occurs when blood cells don't form properly in your bone marrow. Instead, young cells called blasts multiply and crowd out normal healthy cells. This is what causes the symptoms of AML.

**Blast (or myeloblast):** A young, abnormal, cancerous cell that does not mature into a healthy blood cell in your bone marrow.

**Bone marrow:** The soft interior of bones where blood cells are created.

**Consolidation therapy:** A high-dose, intense chemotherapy given after AML is in remission. Not all people receive consolidation therapy.

**Continued treatment:** A long-term treatment for people not planning to have a transplant. The goal of continued treatment is to kill cancer cells that may be left behind after remission. ONUREG® is a continued treatment.

**Neutropenia:** Lower-than-normal levels of neutrophils (a type of white blood cell), as measured on a blood test. When you have neutropenia, your body has a harder time fighting infections.

**Overall survival:** The length of time that a person lives after starting a medication in a clinical trial.

**Median overall survival:** The length of time after starting a medication in a clinical trial when half the people are still alive.

**Placebo:** An inactive treatment that resembles a real medicine. Real medicines may be compared to placebos in clinical trials.

**Platelet (or thrombocyte):** Small cells in your blood that form clots and stop or prevent bleeding.

**Remission:** The absence of AML signs and symptoms after initial treatment. Being in remission means that less than 5% of your bone marrow contains young, abnormal blood cells (or blasts).

**Complete remission:** When less than 5% of your bone marrow contains blasts, and all your blood counts are normal.

#### Complete remission with incomplete blood count recovery:

When less than 5% of your bone marrow contains blasts, but some of your blood counts have still not returned to normal.

**Thrombocytopenia:** Low platelet count on a blood test. Thrombocytopenia can put you at risk for bleeding.

**Transplant:** An intense procedure that replaces unhealthy stem cells in your bone marrow with healthy cells. Transplant may offer the possibility of a cure for some people with AML.

White blood cell (or leukocyte): A type of blood cell that is part of the body's immune system. White blood cells protect you against illness and disease.



# Important facts about ONUREG® (azacitidine)

This is a summary of important information that you need to know about ONUREG. Your healthcare provider can work with you to help answer any questions you may have about this medication.

Keep this information in a safe place so you can refer to it before and during your treatment.

#### What is ONUREG?

ONUREG (azacitidine) is an oral prescription medicine used to treat adults with **acute myeloid leukemia** (**AML**) who:



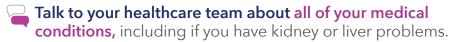
It is not known if ONUREG is safe and effective in children under 18 years of age.

Do not take ONUREG if you are allergic to azacitidine or any of the ingredients in ONUREG.



**Talk to your healthcare team** for more information about what it means to be in first complete remission.

## Before taking ONUREG, what should I discuss with my healthcare team?





- Prescription medicines
- Vitamins
- Over-the-counter medicines
- Herbal supplements

These are not all the topics you should discuss with your healthcare team. Talk to your healthcare team about anything you might be unsure of before starting treatment.

## Before taking ONUREG, what should I discuss with my healthcare team about potential serious fertility side effects, pregnancy, birth control, and breastfeeding?



Talk to your healthcare team about fertility planning, birth control, and the best way to feed your baby during treatment with ONUREG.



If you are pregnant, plan to become pregnant, or your partner plans to become pregnant: ONUREG may harm your unborn baby.

If you are female (sex assigned at birth):

If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ONUREG. You should use effective birth control (contraception) during treatment and for at least 6 months after your last dose of ONUREG. If you are male (sex assigned at birth) with a sexual

partner who can become pregnant:

You should use effective birth control (contraception) during treatment and for at least 3 months after your last dose of ONUREG.

ONUREG may cause fertility problems in all genders and may affect your ability to have children. Talk to your healthcare team if fertility problems are a concern for you.



If you are breastfeeding or plan to breastfeed: It is not known if ONUREG passes into your milk.

Do not breastfeed during treatment and for 1 week after your last dose of ONUREG.

Call your healthcare provider right away if you or your partner becomes pregnant during treatment with ONUREG.

## What are the serious side effects of ONUREG?

ONUREG can cause serious side effects. A serious side effect is a side effect that can be life-altering or can sometimes become life-threatening and can lead to hospitalization or death. The serious side effects of ONUREG may include:

New or worsening low white blood cell counts (neutropenia). New or worsening low white blood cell counts are common but can also be severe during treatment with ONUREG. If your white blood cell counts become very low, you are at higher risk for infections. Your healthcare provider will check your white blood cell counts before and during treatment with ONUREG. If needed, your healthcare provider may prescribe a medicine

- Call your healthcare provider right away if you have any of the following symptoms:
  - Fever or chills
  - Feeling very tired or weak

to help increase your white blood cell count.

- Body aches
- Headaches that are different from what you are used to

### New or worsening low platelet counts (thrombocytopenia).

Low platelet counts are common but can also be severe during treatment with ONUREG. Your healthcare provider will check your platelet counts before and during treatment with ONUREG.

Call your healthcare provider right away if you have any unusual bruising or bleeding.

### What are the most common side effects of ONUREG?

The most common side effects of ONUREG can include:

- Nausea and vomiting
- Diarrhea
- Feeling tired or weak
- Constipation
- Pain in the stomach (abdominal) area

- Pneumonia
- Joint pain
- Decreased appetite
- Pain in your arms or legs
- Feeling dizzy



Talk to your healthcare team if you experience nausea, vomiting, or diarrhea while you are taking ONUREG.

- For nausea and vomiting: You will be prescribed an anti-nausea medication to take before each dose of ONUREG. Talk to your healthcare provider if you haven't been prescribed an anti-nausea medication. If you do not have any nausea or vomiting after your second treatment cycle of ONUREG, your healthcare provider may decide to stop the anti-nausea medication.
- For diarrhea: If you experience diarrhea, you may be treated with anti-diarrheal medication.

These are not all of the possible side effects of ONUREG.



Talk to your healthcare team for more information or advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.



### How will I take ONUREG?

Take ONUREG exactly as your healthcare provider tells you. The recommended dose of ONUREG is one 300 mg tablet taken by mouth 1 time a day for weeks 1 and 2 of each treatment cycle. If you develop certain side effects, your healthcare provider may pause your treatment, decrease your dose, or decrease the number of treatment days. If your side effects persist, your healthcare provider may ask you to stop taking ONUREG permanently.



You will take ONUREG® in treatment cycles that repeat every 4 weeks:

- During weeks 1 and 2: Take 1 tablet by mouth, 1 time each day
- During weeks 3 and 4: Do not take any ONUREG
- Do take ONUREG with or without food
- Do take an anti-nausea medication 30 minutes before your ONUREG dose as prescribed by your healthcare provider
- **Do** take ONUREG at about the same time each day
- **Do** swallow ONURFG tablets **whole**
- Do not cut, crush, or chew ONUREG tablets

### What if I vomit or miss a dose of ONUREG?

Do not take an extra dose.

- If you forget to take your dose at your regularly scheduled time: Take the dose as soon as possible that day. Do not take 2 doses on the same day. Take your next dose at the regularly scheduled time the next day.
- If you vomit after taking a dose of ONUREG: Do not take another dose on the same day. Take your next dose at the regularly scheduled time the next day.



Setting an alarm clock or a calendar notification is a great way to remember to take medication.

**ONUREG** is available in two different tablets. ONUREG tablets are oval with a colored coating. Each tablet is marked with the letters 'ONU' on one side and the numbers '300' or '200' on the other.



OR



Note: Images do not represent actual tablet sizes

## **Inactive ingredients:**

• All ONUREG tablets contain: croscarmellose sodium. magnesium stearate, mannitol, silicified microcrystalline cellulose, hypromellose, iron oxide red, lactose monohydrate, polyethylene glycol, titanium dioxide, and triacetin

For more information, please see enclosed **full Prescribing Information** for ONUREG. Talk to your healthcare provider for more information about this medication.

## What if I vomit or miss a dose of ONUREG? (cont'd)

- The brown 300 mg tablet coating also contains: black iron oxide, iron oxide yellow
- The powder inside ONUREG tablets should not come in contact with your skin, eyes, or mouth. Do not cut, crush, or chew ONUREG tablets. Do not take broken or damaged tablets. If the powder comes in contact with your:
  - eyes or mouth (mucous membranes): flush the area right away with water
  - skin: wash the area right away with soap and water

### What else should I know about ONUREG?

**Do not** use ONUREG for a condition that it is not prescribed for. Sometimes ONUREG is prescribed for purposes other than those mentioned in the Patient Information leaflet.

**Do not** give ONUREG to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare team for information about ONUREG that is written for healthcare providers.

## How should I store ONUREG®?

Keep your ONUREG tablets in the containers they came in.

Store tablets at **room temperature** between 68°F to 77°F (20°C to 25°C).

Keep ONUREG and all medicines out of reach of children.

# How do I get rid of any unused or expired ONUREG?



**Talk to your healthcare team** about how to safely throw away (dispose of) any unused or expired ONUREG.

for more information, please see enclosed **full Prescribing Information** for ONUREG. Talk to your healthcare provider for more information about this medication.



\*In a clinical trial, people with AML who took ONUREG lived longer overall than people who took placebo (an inactive medicine). Median overall survival was 24.7 months with ONUREG vs 14.8 months with placebo. Learn more about the trial on page 6 of this brochure.

†Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed March 26, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

#### What is ONUREG?

ONUREG (azacitidine) is an oral prescription medicine used to treat adults with <u>acute myeloid leukemia</u> (<u>AML</u>) who:

Are in first **c**omplete **r**emission (**CR**) (with or without recovery of your blood cell counts) after intensive induction chemotherapy **and** are not able to complete intensive curative therapy.

It is not known if ONUREG is safe and effective in children under 18 years of age.

Do not take ONUREG if you are allergic to azacitidine or any of the ingredients in ONUREG.

Talk to your healthcare team for more information about what it means to be in first complete remission.

Please see additional Important Safety Information throughout and <u>click here</u> for full Prescribing Information for ONUREG®.



