

ONUREG® is a prescription medicine used for continued treatment of adults with acute myeloid leukemia (AML) who had a first complete remission (CR) following intensive induction chemotherapy with or without recovery of your blood cell counts, and who 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.



Now that your AML is in first remission...

FOR ADULT PATIENTS

A GUIDE TO STARTING



ONUREG[™]
(azacitidine) tablets
300mg • 200mg

Do not take ONUREG® if you:

are allergic to azacitidine or any of the ingredients in ONUREG®.
See the Patient Information for a complete list of ingredients in ONUREG®.

Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG®.



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Before taking ONUREG[®], talk to your healthcare provider

What should I tell my doctor before taking ONUREG[®]?

Before taking ONUREG[®], tell your healthcare provider about all of your medical conditions, including if you:

- Have kidney or liver problems
- Are pregnant or plan to become pregnant. ONUREG[®] can harm your unborn baby
 - **Females who are able to become pregnant:**
 - Your healthcare provider should perform 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[®]
 - Tell your healthcare provider right away if you become pregnant during treatment with ONUREG[®]
 - **Males with a female 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[®]
- Are breastfeeding or plan to breastfeed. It is not known if ONUREG[®] passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of ONUREG[®]

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



See [page 19](#) for important questions to ask your healthcare team

Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG[®].

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You and your healthcare team have decided that ONUREG® is right for you

This guide will help explain AML and your course of treatment with ONUREG®. Here's what you'll find inside:

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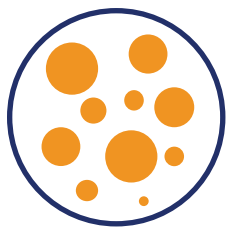
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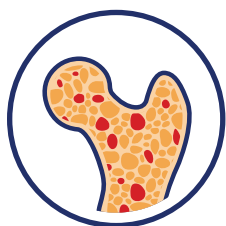
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What is acute myeloid leukemia?



AML is a blood cancer that starts in the bone marrow

The **bone marrow** is a soft tissue found within the bones. Bone marrow typically produces **platelets** (which help with blood clotting), **red blood cells** (which transport oxygen throughout the body), and **white blood cells** (which help fight infection). In most cases, AML can quickly move from the bone marrow into the blood and can sometimes spread to other parts of the body.



In AML, the bone marrow makes abnormal blood cells

Normally, the bone marrow makes immature cells that go on to become mature blood cells. In AML, blood cells don't form properly in the bone marrow and young, immature cells, called myeloblasts, or "**blasts**" for short, are produced instead. Blasts are unable to fight infections the way healthy blood cells can.

As the bone marrow produces more and more blasts, there is no room for the production of normal platelets, red blood cells, and white blood cells. When there are too many blasts and not enough healthy cells, the symptoms of AML begin to occur.



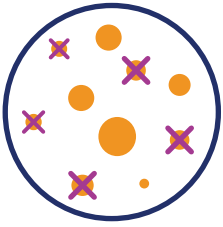
Treatment for someone with AML typically starts as soon as possible

"**Acute**" means that this disease can get worse quickly if left untreated. Depending on factors like age or the type of AML, a person with AML may receive a few treatments before they start to feel better.



Learn more about AML with helpful definitions in the glossary on [page 22](#)

What is acute myeloid leukemia? (cont'd)



A main goal of treatment is to eliminate the blasts in the blood and bone marrow

The first phase of treatment, called **induction therapy**, is usually the strongest against blasts. The goal of induction therapy is to achieve **complete remission**. Complete remission, or remission for short, describes the absence of signs and symptoms of AML.*



Your healthcare team will decide if treatment after remission is necessary

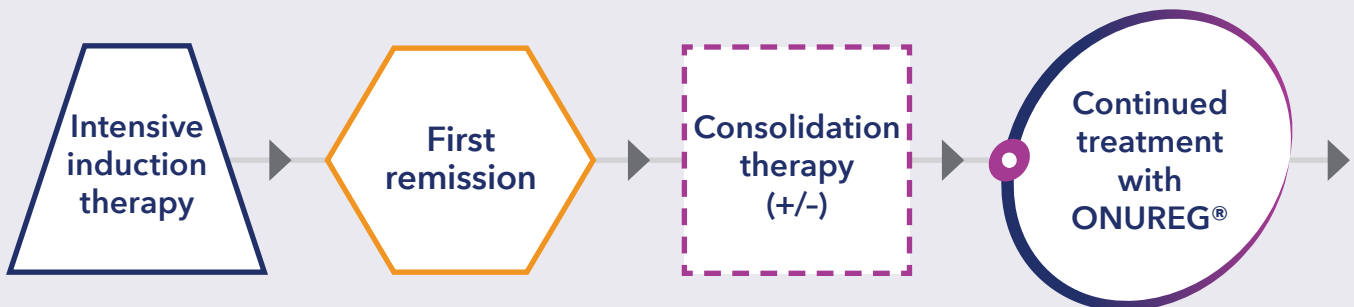
Goals of treatment may include preventing AML from returning and helping patients live longer.*

Post-remission treatment options include:

- **Additional chemotherapy:** Consists of similar drugs used during induction, however, at different doses. This treatment is also known as **consolidation therapy**
- **Bone marrow transplant:** Involves transferring healthy stem cells from a donor to a person with AML. This treatment is also known as a **stem cell transplant** or a **hematopoietic stem cell transplant**

Continued treatment is another post-remission option for AML

Potential treatment journey for people with AML



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What is ONUREG®?

ONUREG® is the first FDA-approved continued treatment for people with AML who are in first remission

ONUREG® is a prescription medicine used for continued treatment of adults with acute myeloid leukemia (AML) who had a first complete remission (CR) following intensive induction chemotherapy with or without recovery of your blood cell counts, and who are not able to complete intensive curative therapy.

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What is ONUREG®? (cont'd)

How does ONUREG® work?

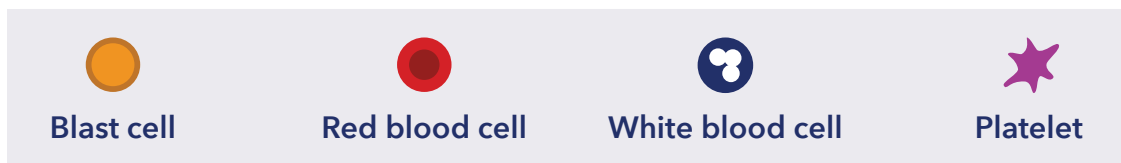
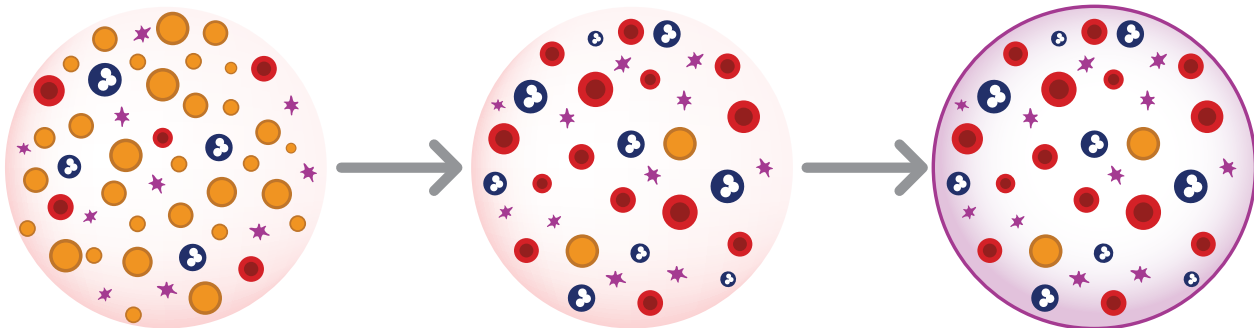
In preclinical studies, ONUREG® stopped AML cells from growing and increasing in number. In these studies, ONUREG® worked by incorporating itself into the DNA and RNA of cancer cells, and this may help reactivate certain genes and help kill the cancer cells.

ONUREG® is given to people in first remission.

Before receiving induction therapy with/without consolidation treatment

After receiving induction therapy with/without consolidation treatment

During AML continued treatment with ONUREG®



Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG®.

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What are the possible benefits of ONUREG®?

A clinical trial was done to determine the safety and effectiveness of ONUREG®

ONUREG® was studied in 472 people with AML who achieved first remission (had no signs or symptoms of AML) following intensive induction therapy with or without consolidation therapy, who were 55 years or older, and who did not proceed to transplant.

- **238 people** were randomly assigned to receive ONUREG®
- **234 people** received **placebo**

The main goal of the trial was to determine how much longer adults with AML in first remission could live when taking ONUREG® compared with placebo



Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG®.

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What are the possible benefits of ONUREG®? (cont'd)

*In the clinical trial,
people with AML taking ONUREG®
lived longer overall than people taking placebo*



24.7
MONTHS

**MEDIAN OVERALL
SURVIVAL WITH
ONUREG®**

MEDIAN OVERALL SURVIVAL

ONUREG®
24.7
MONTHS

VS

Placebo
14.8
MONTHS

Approximately 10 months difference vs placebo

Overall survival refers to how long people in a clinical trial stayed alive after beginning treatment. The median is the middle number. This means that half of people who took ONUREG® were alive 24.7 months after the beginning of treatment, which is over 2 years.

Please see full [Prescribing Information](#)
and [Patient Information](#) for ONUREG®.

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What are the possible side effects of ONUREG®?

ONUREG® can cause serious side effects, including:

New or worsening low white blood cell counts (also known as 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 increased risk for infections. Your healthcare provider 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.

Tell your healthcare provider right away if you get any of the following symptoms:

- Fever or chills
- Body aches
- Feeling very tired or weak
- Unusual headaches

New or worsening low platelet counts (also known as 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®. Tell your healthcare provider right away if you have any unusual bruising or bleeding. Your healthcare provider may change your dose or tell you to stop taking ONUREG® if you have low blood cell counts.

What are the possible side effects of ONUREG®? (cont'd)

Fertility problems

ONUREG® may cause fertility problems in males and females, which may affect your ability to have children. Talk with your healthcare provider if you have concerns about fertility.

The most common side effects of ONUREG® include:

- Nausea and vomiting
- Diarrhea
 - You may need to be treated with anti-diarrheal medicines
- Tiredness or weakness
- Constipation
- Stomach area (abdominal) pain
- Pneumonia
- Joint pain
- Decreased appetite
- Pain in arms or legs
- Dizziness

Side effects during cycles 1-2 of ONUREG®

In the clinical trial for ONUREG®, nausea, vomiting, and diarrhea were most common during the first 2 cycles of treatment. These side effects may improve over time and experiences may vary.

Talk to your healthcare provider about what to expect with ONUREG®. They will prescribe medication to help prevent nausea and vomiting during treatment, and may stop it after 2 cycles if you do not have these side effects. You may also be prescribed medication to help with diarrhea, if necessary.

These are not all of the possible side effects of ONUREG®. Call your healthcare provider for medical advice about side effects.

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

Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG®.

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How should I take ONUREG®?

The recommended dosage is one 300 mg tablet orally, once daily with or without food, for 14 days of every 28-day treatment cycle

2 WEEKS ON



2 WEEKS OFF



- Your healthcare provider will prescribe an anti-nausea medicine for you to take to help prevent nausea and vomiting during your treatment with ONUREG®
 - Take the anti-nausea medicine 30 minutes before each dose of ONUREG®
 - Your healthcare provider may decide to stop the anti-nausea medicine after your second cycle of ONUREG®, if you do not have any nausea or vomiting
- If you miss a dose of ONUREG®, or if you do not take your dose at the usual time, take the dose as soon as possible that day. Take your next dose at the regular time the next day. Do not take 2 doses on the same day to make up for a missed dose
- If you vomit after taking a dose of ONUREG®, do not take another dose on the same day. Take your next dose at the regular time the next day

ONUREG® is supplied in a blister card containing **7 tablets**. You will receive **2 blister cards** for each cycle of treatment.



Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG®.

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How should I take ONUREG®? (cont'd)

ONUREG® is an oral medication that you can take at home or wherever is convenient for you



Take ONUREG® exactly as your healthcare provider tells you to take it



Take ONUREG® by mouth 1 time each day



Your healthcare provider will prescribe an anti-nausea medication to take with ONUREG®

- Take it 30 minutes before each dose of ONUREG®
-



Swallow ONUREG® tablets whole. Do not cut, crush, or chew the tablets

- 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
-



Take ONUREG® with or without food at about the same time each day



Please see full [Prescribing Information](#) and [Patient Information](#) for ONUREG®.

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Quick tips for taking ONUREG[®]

How can I remember to take ONUREG[®] every day?

One ONUREG[®] tablet should be taken by mouth once a day.

Here are some ways that people remember to take oral medications, like ONUREG[®], at about the same time each day

ROUTINE



Make taking your medication part of your daily routine. For example, take your medication right after dinner or before bed*

*ONUREG[®] can be taken with or without food.

REMINDERS



Add a daily reminder on your smartphone/add to your phone's calendar app

SCHEDULE



Create a system to schedule and track your medication

SUPPORT



Involve others to help you take your medication

Quick tips for taking ONUREG[®] (cont'd)

What if I experience side effects?

Consider the following tips if you experience any of the common side effects of ONUREG[®]. Talk to your healthcare team about side effects and discuss if these tips could be appropriate for you.

Fatigue

- ✓ Rest. Take short naps (less than 30 minutes)
- ✓ Talk to your healthcare team about moderate exercise
- ✓ Get enough sleep at night

Nausea and vomiting

- ✓ Ask your healthcare provider about anti-nausea drugs
- ✓ Do relaxation exercises, such as meditation or breathing exercises
- ✓ Eat snacks or small meals during the day to keep something in your stomach

Diarrhea

- ✓ Ask your healthcare provider if you should take medicine for diarrhea
- ✓ Stay hydrated
- ✓ Talk to your healthcare provider about any helpful changes you can make to your diet



Remember, if you have any concerns about side effects you may experience while taking ONUREG[®], talk to your healthcare team

How should I store ONUREG®?

Keep ONUREG® and all medicines out of the reach of children

Store ONUREG® tablets in the original blister card at room temperature between 68°F to 77°F (20°C to 25°C)

- ONUREG® is supplied in a blister card containing 7 tablets. Take ONUREG® exactly as your healthcare provider tells you to take it
- Talk to your healthcare provider or pharmacist about how to safely throw away (dispose of) any unused or expired ONUREG®



General information about the safe and effective use of ONUREG®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ONUREG® for a condition for which it was not prescribed. Do not give ONUREG® to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about ONUREG® that is written for health professionals.



For more information, visit [ONUREG.com/mytreatment](https://www.onureg.com/mytreatment)

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Important questions to ask your healthcare team

Why is ONUREG[®] right for me?

What are the most important things I need to know about ONUREG[®]?

What should I expect while taking ONUREG[®]?

Are there side effects that I should watch out for?

Is there something you could give me if I experience nausea, vomiting, or diarrhea?

Are there things that I should not do while taking ONUREG[®]?

Where and how do I take ONUREG[®]?

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

How long will it take for ONUREG[®] to start working? How will I know if it's working?

BMS Access Support® Can Provide Patient Access and Reimbursement Assistance

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.



How BMS Access Support May Help

Find out how BMS can work with patients and their healthcare providers to help access a prescribed BMS medication.



Financial Support Options

There may be programs and services that could help with the cost of treatment. Learn about what options are available.



Additional Resources

We provide videos, tools, and other resources that may help with your access and reimbursement needs.

Have Questions About Our Program or Possible Financial Support?

If you have questions about coverage for a prescribed BMS medication, BMS Access Support may be able to help. Patients and their healthcare provider can complete an enrollment form to learn about programs that may be of assistance. Visit our website or contact BMS Access Support to learn more.



Call Bristol Myers Squibb Access Support at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday



Visit www.BMSAccessSupport.com

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Helpful resources for people with AML

Here are some additional links that may provide more resources. Bristol Myers Squibb takes no responsibility for the content of these resources.

American Cancer Society	www.cancer.org/cancer/acute-myeloid-leukemia.html WhatNext Support Network: www.whatnext.com (800) 227-2345
Blood & Marrow Transplant Information Network	www.BMTinfonet.org (847) 433-3313 (888) 597-7674
CancerCare	www.cancercare.org (800) 813-HOPE (4673)
Cancer.net	www.cancer.net (571) 483-1780 (888) 651-3038
Cancer Support Community	www.cancersupportcommunity.org (888) 793-9355
Know AML	www.know-aml.com
The Leukemia & Lymphoma Society® (LLS)	www.lls.org/leukemia/acute-myeloid-leukemia Chapter finder: www.lls.org/chapter-selection-page (800) 955-4572
MDS Foundation - You and AML	www.mds-foundation.org/what-is-aml
National Cancer Institute at the National Institutes of Health	www.cancer.gov/resources-for/patients (800) 422-6237 (1-800-4-CANCER)

Please see full **Prescribing Information** and **Patient Information** for ONUREG®.



Glossary

Acute: An illness that will progress quickly if left untreated

Blasts: Young, immature cells that build up in the bone marrow. They are unable to fight infections the way healthy, mature white blood cells can. Also known as myeloblasts

Bone marrow: The soft interior of the bones where new blood cells are created

Bone marrow transplant: A type of transplant that involves transferring healthy stem cells from a donor to a person with AML. This treatment is also known as a stem cell transplant or a hematopoietic stem cell transplant

Complete remission/remission: The absence of signs and symptoms of AML

Consolidation therapy: Additional chemotherapy treatment that may be given after induction. Consolidation therapy consists of similar drugs used during induction, however, at different doses

Continued treatment: Medication used in a person with AML in first remission, after the first phase of cancer treatment, over an extended period of time

Intensive induction therapy: The first phase of treatment a person with AML receives. This treatment is usually the strongest against blast cells

Neutropenia: A low number of neutrophils (a type of white blood cell)

Placebo: An inactive substance that has no therapeutic effect but may be used to compare the effects of an active drug

Platelets: Help prevent bleeding caused by cuts and bruises (help with blood clotting)

Post-remission treatment: Treatment that is given to continue to keep a person with AML in remission and can help prevent AML from returning

Red blood cells: Carry oxygen from the lungs to all cells in the body

Stem cell transplant: See "Bone marrow transplant" above

Thrombocytopenia: A low number of platelets

White blood cells: Help the body fight infections. They are a crucial part of the body's immune system



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