READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrONUREG®
azacitidine tablets

Read this carefully before you start taking **ONUREG®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ONUREG®.**

What is ONUREG® used for?

ONUREG® is for use in adults that have no more signs (remission) of a blood cancer called acute myeloid leukemia (AML). ONUREG® maintains remission of AML in patients:

- who may or may not have received an additional phase of chemotherapy (consolidation therapy), and
- who are not able to receive a stem cell transplant.

How does ONUREG® work?

ONUREG® helps prevent cancer cells from growing. Azacitidine disrupts the production of new genetic building blocks of cells. This helps kill cancer cells in leukemia, a type of blood cancer.

Talk to your healthcare professional if you have any questions about how ONUREG® works or why this drug has been prescribed for you.

What are the ingredients in ONUREG®?

Medicinal ingredients: azacitidine

Non-medicinal ingredients: black iron oxide, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, polyethylene glycol/macrogol, magnesium stearate, mannitol, silicified microcrystalline cellulose, titanium dioxide, triacetin

ONUREG® comes in the following dosage forms:

Tablets: 200 mg or 300 mg

Do not use ONUREG® if:

- You are allergic to any ingredients in this drug or the container.
- You have advanced liver cancer.
- You have a blood cancer called myelodysplastic syndrome (MDS) unless you are participating in a controlled trial.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ONUREG®. Talk about any health conditions or problems you may have, including if you:

- are pregnant, or you or your partner are planning on getting pregnant
- are breastfeeding or planning to breastfeed. You should not breastfeed while taking ONUREG®.
- Have a blood cancer called myelodysplastic syndromes (MDS).
- Have kidney or liver problems.

- Have heart problems.

Other warnings you should know about:

- ONUREG® is not switchable with, and should not be substituted with or for, azacitidine for injection.

Fertility:
- ONUREG® may harm fertility in males and females. If you wish to have or father children, talk to your healthcare professional about ways to keep your fertility before you start treatment

Female Patients: Important Warnings
- ONUREG® should not be used if you are pregnant. ONUREG® may cause harm to your unborn baby.
- If you can get pregnant, your healthcare professional will do a pregnancy test before starting ONUREG®.
- If you are pregnant or become pregnant while taking ONUREG®, tell your healthcare professional right away. They will explain the risks to you.
- You must use an effective birth control methods while taking ONUREG® and for at least 6 months after your last dose. Talk to your healthcare professional about birth control methods that may be right for you.

Breast-Feeding:
- Do not breastfeed during treatment with ONUREG® and for at least one week after the last dose. It is not known if ONUREG® passes into the mother's milk.

Male Patients: Important Warnings
- While taking ONUREG® and for at least 6 months after your last dose:
    - Your female partner should not get pregnant by you, and
    - You must use an effective birth control methods. Talk to your healthcare professional about birth control methods that may be right for you.

ONUREG® can cause serious side effects, including:
- **Stomach problems such as nausea, vomiting and diarrhea.** Your healthcare professional may give you drugs to treat or prevent these symptoms.
- **Blood problems:** ONUREG® can cause **neutropenia** (low levels of white blood cells, sometimes with a fever) and **thrombocytopenia** (low levels of platelets). Your healthcare professional may adjust how you take ONUREG® if you experience these side effects.

  For more information on these and other serious side effects, (their) symptoms and what to do about them, see the "Serious side effects and what to do about them" table. The table can be found later in this Patient Medication Information.

Driving and Using Machines: Before you do tasks which may require special attention, wait until you know how you respond to ONUREG®. If you feel tired, weak or have stomach problems, do not drive or use tools or machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ONUREG®:

No relevant interactions are known.

How to take ONUREG®:

- To prevent nausea and vomiting, your healthcare professional may recommend you take another drug before you take your dose of ONUREG®. Your healthcare professional will review the ongoing need for this additional drug.
- Take ONUREG® as your healthcare professional tells you.
- Take ONUREG® by mouth at about the same time each day.
- Swallow the tablets whole with water. Do not split, crush or chew the tablets.
- Take ONUREG® with or without food.
- Do not take more than the recommended dose prescribed by your healthcare professional.
- Do not change the ONUREG® dose or schedule unless your healthcare professional tells you to.

Recommended Dose:
Adults:

- Take 300 mg once daily. ONUREG® is taken for 14 days followed by a rest period of 14 days. This treatment cycle will be repeated every 28 days.
- Your healthcare professional will monitor your health. They may interrupt, reduce or stop your dose. This may occur based on your current health, if you take certain other medications or if you have certain side effects.

Overdose:

If you think you have taken too much ONUREG®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If a dose of ONUREG® is missed or not taken at the usual time:

- Take the missed dose as soon as you remember. Take the next dose at your regular time on the next day.
- Do not take two doses on the same day.
- If you vomit after taking a dose of ONUREG®, do not take another dose on that same day. Take your next dose at your regular time on the next day.

What are possible side effects from using ONUREG®?

These are not all the possible side effects you may feel when taking ONUREG®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- anxiety
- tiredness / weakness
- constipation
- stomach area pain

- excess gas
- pain in your joints, back, arms and/or legs
- decreased appetite
- dizziness

Your healthcare professional will do some tests before, during and after your treatment. These include blood tests to check your blood cell count. More frequent tests might be needed. They will tell you if your test results are abnormal and if you need treatment.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Neutropenia or Leukopenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms		√	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		√	
Nausea, vomiting, diarrhea		√	
COMMON			
Pneumonia (infection in the lungs): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath			√
Syncope (fainting)**:** a temporary loss of consciousness due to a sudden drop in blood pressure		√	
Upper respiratory tract infection (a cold or flu): runny or stuffy nose, sore throat, cough, sinus congestion, body aches, headache, sneezing, fever, generally feeling unwell		√	
Urinary tract infection (infection in urinary system including kidneys, ureters,		√	

bladder and urethra): Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store blisters at 15°C to 30°C. Store in the original aluminum blisters.

Wash your hands and skin with soap and water right away after contact with ONUREG® tablets. If tablets come in contact with mucous membranes (soft, moist areas inside the openings of your body), flush the area with water right away.

Keep out of reach and sight of children.

Do not throw away any drugs via wastewater or household waste. Ask your pharmacist how to throw away drugs you no longer use.

If you want more information about ONUREG®:
- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp); the manufacturer's website www.bms.com/ca/en, or by calling1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada, Montreal, Canada H4S 0A4

® ONUREG is a registered trademark of Celgene Corporation used under license by Bristol-Myers Squibb Canada.

Last Revised: FEB 29, 2024