ONUREG®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Onureg?

Onureg contains the active ingredient azacitidine. Onureg is used to treat adults with a certain type of leukaemia called acute myeloid leukaemia (AML). For more information, see Section 1. Why am I given Onureg? in the full CMI.

2. What should I know before I use Onureg?

Do not take this medicine if you are allergic to the active ingredient in Onureg (azacitidine) or any of the ingredients listed at the end of the CMI.

Do not use Onureg if you plan to become pregnant, are pregnant or breastfeeding.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Onureg? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Onureg and affect how it works. Onureg may also affect the way some other medicines work. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Onureg?

- Onureg tablets should be taken exactly as your doctor has told you. Check with your doctor if you are not sure about how much you should take or how often you should take this medicine. More instructions can be found in Section 4. How do I use Onureg? in the full CMI.

5. What should I know while using Onureg?

Things you should do	• Remind any doctor, dentist or pharmacist

	you visit that you are using Onureg. • Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant. • Tell your doctor, pharmacist or nurse straight away if you get any of these symptoms during treatment with Onureg: bruising or bleeding - this could be due to a low count of blood cells called “platelets”; fever - this could be due to an infection as a result of having low levels of white blood cells - which can be life- threatening; diarrhoea; being sick or a feeling of sickness.
Things you should not do	• Do not use if you have ever had an allergic reaction to Onureg or any of the ingredients listed at the end of the CMI. Do not breast feed whilst taking Onureg. Do not use this medicine

	during pregnancy as it may be harmful to your baby.
Driving or using machines	• This medicine may cause tiredness, weakness or trouble concentrating. If you have any of these symptoms or other side effects, do not drive, operate machinery or do anything else that could be dangerous.
Looking after your medicine	• Store the tablets in the original package. • Store below 25°C.

For more information, see Section 5. What should I know while using Onureg? in the full CMI.

6. Are there any side effects?

Like all medicines, Onureg can have side effects, although not everybody gets them, and some are uncommon. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. If you experience bruising or bleeding; fever; diarrhoea, being sick or have a feeling of sickness. contact your doctor immediately, or go to the Emergency Department at your nearest hospital. For more information, including what to do if you have any

side effects, see Section 6. Are there any side effects? in the full CMI.

ONUREG®

Active ingredient(s): azacitidine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Onureg. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Onureg.**

Where to find information in this leaflet:

1. Why am I using Onureg?
2. What should I know before I use Onureg?
3. What if I am taking other medicines?
4. How do I use Onureg?
5. What should I know while using Onureg?
6. Are there any side effects?
7. Product details

1. Why am I given Onureg?

Onureg contains the active ingredient azacitidine.

Azacitidine works by preventing cancer cells from growing. Azacitidine gets into the genetic material of cells (called RNA and DNA). It works by altering the way the cell turns genes on and off. It also reduces the

production of new RNA and DNA. This is thought to kill cancer cells in leukaemia.

Onureg is used to treat adults with a certain type of leukaemia called acute myeloid leukaemia (AML). This is a form of cancer which affects your bone marrow and can cause problems with producing normal blood cells. Onureg is used to maintain remission of the illness, the time when the disease is less severe or not active.

2. What should I know before I use Onureg?

Your doctor will conduct a blood test prior to starting you on Onureg and during treatment. This is to check that you have enough blood cells. It is also to check that your liver and kidneys are working properly. Your doctor will decide how often you have blood tests.

Warnings

Do not use Onureg if:

- you are allergic to azacitidine or any of the ingredients of this medicine.
- you are breastfeeding.
- you are pregnant or think you may be pregnant.

Always check the ingredients and speak to your doctor to make sure you can use this medicine.

Check with your doctor if you:

- are pregnant, think you may be pregnant or are planning to become pregnant. Onureg may cause harm to your unborn baby if taken during pregnancy. Your doctor will arrange a pregnancy test before treatment.
- are breastfeeding or planning to breast feed
- are a woman, Onureg may cause fertility problems, which may affect your ability to have a baby. Talk to your doctor for advice before taking Onureg.
- are a man, and are planning to father a child. Men should not father a child while receiving treatment with Onureg.
- are taking, have recently taken or might take any other medicines for any other condition
- are intolerant to lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take Onureg during pregnancy as it may be harmful to your baby.

Do not breast-feed while taking Onureg. It is not known if this medicine passes into human milk.

If you are pregnant, breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You or your partner must use an effective method of contraception during treatment and for 6 months after stopping Onureg. Talk to your doctor about contraceptive methods that may be right for you while you are taking Onureg.

Tell your doctor straight away if you become pregnant during treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Fertility information for men

Men should not father a child while receiving treatment with Onureg.

Use an effective method of contraception during treatment and for 3 months after stopping Onureg.

Use in children or adolescents

- This medicine is not recommended for use in children and adolescents under 18 years.

Onureg contains lactose

- Onureg contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Onureg contains sodium

- This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Onureg.

4. How do I used Onureg?

How much to take

The recommended dose is 300 mg taken by mouth once daily. Your doctor may reduce your dose to 200 mg once daily, if needed.

Onureg is given in treatment cycles of 28 days.

You take Onureg every day for the first 14 days of each 28 day cycle. This is followed by a treatment free period of 14 days for the rest of the cycle.

Your doctor will tell you what dose of Onureg to take. The doctor may decide to:

- extend your treatment beyond 14 days in each treatment cycle
- lower your dose or temporarily stop treatment
- reduce your treatment to 7 days.
- Always take as prescribed by your doctor.

Your doctor will give you another medicine to reduce the risk of feeling sick (nausea) and being sick (vomiting). You will take it 30 minutes before each Onureg tablet, during your first and second treatment cycles. Your doctor will tell you to take it for a longer period, if you need it.

When to take Onureg

Take Onureg once a day - at the same time each day.

If you are sick after taking a tablet, do not take another dose on the same day. Instead, wait till the next day and take your next schedules dose then. Do not take two doses on the same day.

How to take Onureg

- Swallow the Onureg tablets whole with a full glass of water. To make sure you get the right dose, do not break, crush, dissolve or chew the tablets.
- Onureg tablets can be taken with or without food.
- Always take as prescribed by your doctor.
- If powder from a broken tablet gets onto your skin, wash the skin straight away and thoroughly with soap and water. If the powder gets into your eyes, nose or mouth, flush thoroughly the area with water.

If you forget to use Onureg

If you forget to take Onureg at the usual time, take your usual dose as soon as you remember on the same day and take your next dose at the usual time on the following day.

Do not take a double dose to make up for a forgotten or vomited tablet.

Do not stop taking Onureg unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor.

If you use too much Onureg

If you think that you have used too much Onureg, you may need urgent medical attention.

If possible, take the medicine pack and this leaflet with you.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Onureg?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.

- Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Onureg.
- Tell your doctor immediately if you become pregnant while being treated with Onureg
- Advice for women: use an effective method of contraception during treatment and for 6 months after stopping Onureg.
- Advice for men: Use an effective method of contraception during treatment and for 3 months after stopping Onureg.

Call your doctor straight away, or go to the Emergency Department at your nearest hospital if you:

- experience shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching; or hives on the skin. These could be symptoms of a serious allergic reaction.

Things you should not do

- Do not breast feed if you are taking Onureg.
- Do not use this medicine during pregnancy.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Onureg affects you.

Onureg may cause tiredness, dizziness or feeling faint in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Store the tablets in the original package.
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
• bruising or bleeding - this could be due to a low count of blood cells called “platelets”. • fever - this could be due to an • infection of the blood (sepsis), which may be due to low levels of white blood cells. • diarrhoea, being sick or a feeling of sickness. • infection of the lungs • infection of the urinary tract fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness • fainting • flu like symptoms	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Other side effects

Very common side effects	What to do
• constipation • pain in your belly • infections of the nose, sinuses and throat, caused by bacteria or viruses • feeling tired or weak • loss of appetite • pain that affect different parts of the body - this can range from a sharp pain to a dull ache • stiff joints • back pain **Common side effects** • hay fever • anxiety • loss of weight	**Speak to your doctor if you have any of these side effects and they worry you.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects (for example changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Onureg contains

Active ingredient	azacitidine
Other ingredients **(inactive ingredients)** **Onureg 200mg Tablet Coating**	croscarmellose sodium, hypromellose, iron oxide red, lactose monohydrate, polyethylene glycol/ macrogol, magnesium stearate, mannitol, silicified microcrystalline cellulose, titanium dioxide, triacetin

Other ingredients **(inactive ingredients)** **Onureg 300mg Tablet Coating**	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
Potential allergens	Lactose Monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Onureg looks like

Onureg 200 mg film-coated tablets are pink and oval shaped with “200” imprinted on one side and “ONU” on the other side (Aust R 370367).

Onureg 300 mg film-coated tablets are brown and oval shaped with “300” imprinted on one side and “ONU” on the other side (Aust R 370372).

Who distributes Onureg in Australia

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave

Victoria 3170, Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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