Package leaflet: Information for the user

Onureg 200 mg film-coated tablets
Onureg 300 mg film-coated tablets
azacitidine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Onureg is and what it is used for

What Onureg is
Onureg is an anti-cancer medicine that belongs to a group of medicines called anti-metabolites. Onureg contains the active substance azacitidine.

What Onureg is used for
Onureg is used to treat adults with 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 keep the disease in control (remission, when the disease is less severe or not active).

How Onureg works
Onureg works by preventing cancer cells from growing. Azacitidine, the active substance in Onureg, works by altering the way the cell turns genes on and off. It also reduces the production of new genetic material (RNA and DNA). These effects are thought to block growth of cancer cells in leukaemia.

Talk to your doctor or nurse if you have any questions about how Onureg works or why this medicine has been prescribed for you.

2. What you need to know before you take Onureg

Do not take Onureg
- if you are allergic to azacitidine or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions

Blood tests
You will have blood tests before you begin treatment with Onureg and during treatment with Onureg to check that you have enough blood cells and that your liver and kidneys are working properly. Your doctor will decide how often you have blood tests.

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, vomiting or nausea (feeling sick).

Your doctor may need to change the dose, interrupt treatment or stop treatment with Onureg completely. The doctor may prescribe other medicines to help manage these symptoms.

Children and adolescents
Onureg is not recommended for use in children and adolescents below the age of 18.

Other medicines and Onureg
Tell your doctor if you are taking, have recently taken or might take any other medicines. This is because Onureg may affect the way some other medicines work. Also, some other medicines may affect the way Onureg works.

Pregnancy, contraception and breast-feeding
If you are pregnant or breast-feeding, you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Men should not father a child while receiving treatment with Onureg.

Pregnancy
Do not take Onureg during pregnancy as it may be harmful to your baby. Tell your doctor straight away if you become pregnant during treatment.

Contraception
If you are a woman who can become pregnant you should use an effective method of contraception while taking Onureg and for 6 months after stopping treatment with Onureg. Men should use an effective method of contraception while taking Onureg and for 3 months after stopping treatment with Onureg.

Your doctor will discuss with you the most suitable method of contraception for you to use.

Breast-feeding
Do not breast-feed while taking Onureg as it may be harmful to your child.

Fertility
Onureg may affect your ability to have a baby. Talk to your doctor for advice before using it.

Driving and using machines or tools
You may feel tired, weak or have trouble concentrating. If this happens to you or if you have other side effects, do not drive or use any machines or tools.

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 tablet, that is to say essentially 'sodium-free'.

3. How to take Onureg

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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.

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 Onureg as prescribed by your doctor.

Your doctor will give you a medicine that helps to reduce nausea (feeling sick) and vomiting. You 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.

Taking this medicine
- Take Onureg once a day - at the same time each day.
- Swallow the 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.
- You can take the medicine with food or between meals.

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

If powder from a broken tablet touches your skin, wash the skin straight away and thoroughly with soap and water. If the powder gets into your eyes, nose or mouth, flush the area thoroughly with water.

If you take more Onureg than you should
If you take more tablets than you should, contact your doctor or go to a hospital straightaway. If possible, take the medicine pack and this leaflet with you.

If you forget to take 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 the next day. Do not take a double dose to make up for a forgotten or vomited tablet.

If you stop taking Onureg
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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
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, vomiting or nausea (feeling sick).

Other side effects include:

Very common side effects (may affect more than 1 in 10 people):
- constipation
- pain in your belly
- infections of the nose, sinuses and throat
- infection of the lungs
- 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 (may affect up to 1 in 10 people):
- flu
- infection of the urinary tract
- hay fever
- anxiety
- loss of weight.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Onureg

Keep this medicine out of the sight and reach of children.

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.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Onureg contains

- The active substance is azacitidine. Each film-coated tablet contains either 200 mg or 300 mg azacitidine.
- The other ingredients are croscarmellose sodium (E468), magnesium stearate (E572), mannitol (E421), and silicified microcrystalline cellulose (E460, E551).

- The 200 mg tablet coating – Opadry II pink contains: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, polyethylene glycol/macrogols (E1521), triacetin (E1518), and iron oxide red (E172). See section 2 "Onureg contains sodium".

- The 300 mg tablet coating – Opadry II brown contains: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, polyethylene glycol/macrogols (E1521), triacetin (E1518), iron oxide red (E172), iron oxide yellow (E172), and iron oxide black (E172). See section 2 "Onureg contains sodium".

What Onureg looks like and contents of the pack

Onureg 200 mg film-coated tablets are pink and oval shaped with "200" imprinted on one side and "ONU" on the other side.

Onureg 300 mg film-coated tablets are brown and oval shaped with "300" imprinted on one side and "ONU" on the other side.

The film-coated tablets are packaged in aluminium foil blisters.

Each pack contains either 7 or 14 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
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Other sources of information