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Onureg (*azacitidine*)

An overview of Onureg and why it is authorised in the EU

What is Onureg and what is it used for?

Onureg is a cancer medicine used to treat acute myeloid leukaemia (AML), a cancer of white blood cells.

It is used for maintenance treatment after the initial cancer treatment has brought the disease under control, in patients who cannot be given haematopoietic stem cell transplantation (a procedure to replace the cells that produce blood cells) to prevent the cancer coming back.

Onureg contains the active substance azacitidine.

How is Onureg used?

Onureg is available as tablets to be taken by mouth. The medicine can only be obtained with a prescription and treatment must be started and supervised by a doctor experienced in the use of cancer medicines.

Onureg treatment is given in cycles of 28 days. The recommended dose is 300 mg daily for the first 14 days of each cycle, followed by 14 days without the medicine. Treatment is continued until the disease no longer responds or until side effects become unacceptable. The doctor may pause treatment or reduce the dose if certain side effects occur. Patients are also given a medicine to prevent nausea (feeling sick) and vomiting before each dose of Onureg, for at least the first 2 cycles.

For more information about using Onureg, see the package leaflet or contact your doctor or pharmacist.

How does Onureg work?

The active substance in Onureg, azacitidine, belongs to the group 'anti-metabolites'. Azacitidine is an analogue of cytidine (a substance found in RNA and DNA, the genetic material of cells). It is taken up into this genetic material and is thought to act by changing the ability of the cell to turn genes on and off, and also by interfering with the production of new RNA and DNA. These actions are expected to correct problems with the maturation and growth of blood cells in the bone marrow and to help to kill the cancerous cells in leukaemia.

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What benefits of Onureg have been shown in studies?

A main study showed that maintenance treatment with Onureg improves survival in patients with AML who could not be given stem cell transplantation after initial therapy. In this study, involving 472 such patients, patients who received Onureg lived on average around 25 months, compared with about 15 months in those given a dummy treatment (placebo).

What are the risks associated with Onureg?

The most common side effects with Onureg (which may affect more than 1 in 10 people) are nausea (feeling sick), vomiting, diarrhoea, neutropenia (low levels of white blood cells called neutrophils) with or without fever, tiredness, weakness, constipation, thrombocytopenia (low levels of blood platelets), abdominal (belly) pain, respiratory tract infection including pneumonia, arthralgia (joint pain), loss of appetite, pain in the back or limbs, and leucopenia (low levels of white blood cells).

The most common serious side effects are neutropenia with fever and pneumonia but the most common reasons for completely stopping treatment are uncontrollable nausea, vomiting or diarrhoea.

For the full list of side effects and restrictions with Onureg, see the package leaflet.

Why is Onureg authorised in the EU?

Patients with AML whose disease is brought under control but for whom stem cell transplant is not feasible have limited treatment options, and Onureg offers a clinically meaningful improvement in survival. Although the high level of side effects on the digestive system, such as nausea, vomiting and diarrhoea, may reduce the acceptability of the medicine in practice, they were mostly manageable (e.g. by dose adjustments) in patients in the main study. The European Medicines Agency therefore decided that Onureg's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Onureg?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Onureg have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Onureg are continuously monitored. Side effects reported with Onureg are carefully evaluated and any necessary action taken to protect patients.

Other information about Onureg

Onureg received a marketing authorisation valid throughout the EU on 17 June 2021.

Further information on Onureg can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/onureg.

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