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Azacitidine Accord *(azacitidine)*

An overview of Azacitidine Accord and why it is authorised in the EU

What is Azacitidine Accord and what is it used for?

Azacitidine Accord is used for the treatment of adults with the following diseases, if they cannot have haematopoietic stem cell transplantation (when the patient receives stem cells to restore the bone marrow's ability to produce healthy blood cells):

- myelodysplastic syndromes, a group of conditions where too few blood cells are produced by the bone marrow. In some cases, myelodysplastic syndromes can lead to acute myeloid leukaemia (AML, a cancer affecting white blood cells called myeloid cells). Azacitidine Accord is used in patients with an intermediate to high risk of progressing to AML or death;
- chronic myelomonocytic leukaemia (a cancer affecting white blood cells called monocytes). Azacitidine Accord is used when the bone marrow consists of 10 to 29% abnormal cells and the bone marrow is not producing large numbers of white blood cells;
- AML that has developed from a myelodysplastic syndrome and the bone marrow consists of 20 to 30% abnormal cells;
- AML, when the bone marrow has more than 30% abnormal cells.

Azacitidine Accord contains the active substance azacitidine.

Azacitidine Accord is a 'generic medicine'. This means that Azacitidine Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Vidaza. For more information on generic medicines, see the question-and-answer document here.

How is Azacitidine Accord used?

The medicine can only be obtained with a prescription.

Azacitidine Accord treatment should be started and monitored under the supervision of a doctor experienced in the use of cancer medicines. Patients should receive medicines to prevent nausea (feeling sick) and vomiting before receiving Azacitidine Accord.

The recommended dose of Azacitidine Accord depends on the patient's height and weight. It is given as an injection under the skin of the upper arm, thigh or abdomen (tummy) every day for one week, followed by three weeks with no treatment. This four-week period is one 'cycle'. Treatment continues

for at least six cycles and then for as long as it benefits the patient. The liver, kidneys and blood should be checked before each cycle. If the blood counts fall too low or if the patient develops kidney problems, the next treatment cycle should be delayed or a lower dose should be used.

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

How does Azacitidine Accord work?

The active substance in Azacitidine Accord, azacitidine, belongs to the group 'anti-metabolites'. Azacitidine is an analogue of cytidine, which means that it is incorporated into the genetic material of cells (RNA and DNA). It is thought to work by changing the way the cell turns 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 that cause myelodysplastic disorders, and to kill cancerous cells in leukaemia.

How has Azacitidine Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Vidaza, and do not need to be repeated for Azacitidine Accord.

As for every medicine, the company provided studies on the quality of Azacitidine Accord. There was no need for 'bioequivalence' studies to investigate whether Azacitidine Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Azacitidine Accord is the same as the reference medicine and when given by injection under the skin, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Azacitidine Accord?

Because Azacitidine Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Azacitidine Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Azacitidine Accord has been shown to be comparable to Vidaza. Therefore, the Agency's view was that, as for Vidaza, the benefits of Azacitidine Accord outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Azacitidine Accord

Azacitidine Accord received a marketing authorisation valid throughout the EU on 13 February 2020.

Further information on Azacitidine Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/azacitidine-accord. Information on the reference medicine can also be found on the Agency's website.

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