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Azacitidine Kabi (*azacitidine*)

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

What is Azacitidine Kabi and what is it used for?

Azacitidine Kabi 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 the bone marrow produces abnormal blood cells and not enough healthy ones. In some cases, myelodysplastic syndromes can lead to acute myeloid leukaemia (AML, a cancer affecting white blood cells called myeloid cells). Azacitidine Kabi 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 Kabi 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, where the bone marrow consists of 20 to 30% abnormal cells;
- AML, where the bone marrow has more than 30% abnormal cells.

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

Azacitidine Kabi contains the active substance azacitidine.

How is Azacitidine Kabi used?

Azacitidine Kabi can only be obtained with a prescription and 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 Kabi.

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The recommended dose of Azacitidine Kabi depends on the patient's height and weight. It is given as an injection under the skin of the upper arm, thigh or abdomen (belly) every day for 1 week, followed by 3 weeks with no treatment. This 4-week period is one 'cycle'. Treatment is given for at least 6 cycles and, if it is working, it is continued for as long as the patient benefits from it or until the disease gets worse. The liver, kidneys and blood should be checked before each cycle. If blood cell counts are 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 Kabi, see the package leaflet or contact your doctor or pharmacist.

How does Azacitidine Kabi work?

The active substance in Azacitidine Kabi, 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 work by changing the ability of the cell to turn genes on and off and by interfering with the production of new RNA and DNA. These actions are thought to correct the problems with the development of blood cells in the bone marrow that cause myelodysplastic disorders, and to help kill the cancer cells in patients with leukaemia.

How has Azacitidine Kabi 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 Kabi.

As for every medicine, the company provided studies on the quality of Azacitidine Kabi. There was no need for 'bioequivalence' studies to investigate whether Azacitidine Kabi 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 Kabi is the same as that of 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 Kabi?

Because Azacitidine Kabi 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 Kabi authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Azacitidine Kabi has been shown to be comparable to Vidaza. Therefore, the Agency's view was that, as for Vidaza, the benefits of Azacitidine Kabi 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 Kabi?

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

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

Other information about Azacitidine Kabi

Azacitidine Kabi received a marketing authorisation valid throughout the EU on 05 January 2024.

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

This overview was last updated in 01-2024.