EMA/66667/2020
EMEA/H/C/005075

Azacitidine betapharm (*azacitidine*)

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

What is Azacitidine betapharm and what is it used for?

Azacitidine betapharm is used for the treatment of adults with the following diseases, if they cannot have haematopoietic stem cell transplantation (when the patient's bone marrow is replaced to form new bone marrow that produces healthy 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 betapharm 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 betapharm 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 betapharm contains the active substance azacitidine.

Azacitidine betapharm is a 'generic medicine'. This means that Azacitidine betapharm 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 betapharm used?

Azacitidine betapharm 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. Before receiving Azacitidine betapharm, patients should receive medicines to prevent nausea (feeling sick) and vomiting.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The recommended dose of Azacitidine betapharm 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 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 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 betapharm, see the package leaflet or contact your doctor or pharmacist.

How does Azacitidine betapharm work?

The active substance in Azacitidine betapharm, 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 by interfering with the production of new RNA and DNA. These actions are expected to correct problems with the development of blood cells in the bone marrow that cause myelodysplastic disorders and to kill cancerous cells in leukaemia.

How has Azacitidine betapharm 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 betapharm.

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

Because Azacitidine betapharm 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 betapharm authorised in the EU?

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

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

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

Other information about Azacitidine betapharm

Azacitidine betapharm received a marketing authorisation valid throughout the EU on 24 March 2020.

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

This overview was last updated in 03-2020.