EMA/344257/2016
EMEA/H/C/002221

EPAR summary for the public

Dacogen

decitabine

This is a summary of the European public assessment report (EPAR) for Dacogen. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Dacogen.

What is Dacogen?

Dacogen is a powder that is made up into a solution for infusion (drip) into a vein. It contains the active substance decitabine.

What is Dacogen used for?

Dacogen is used to treat adults with newly diagnosed acute myeloid leukaemia (AML), a type of cancer affecting the white blood cells. It is used in patients who are not eligible for standard induction chemotherapy (initial treatment with cancer medicines).

Because the number of patients with AML is low, the disease is considered 'rare', and Dacogen was designated an 'orphan medicine' (a medicine used in rare diseases) on 8 June 2006.

How is Dacogen used?

Dacogen can only be obtained with a prescription. Treatment with Dacogen should be started under the supervision of a doctor who has experience in the use of chemotherapy.

Dacogen is given as an infusion into a vein over one hour. The dose is calculated using the patient's height and weight. In a 4-week treatment cycle, Dacogen is given daily for the first 5 days. At least 4 treatment cycles are recommended but they can be continued for as long as the AML remains under control. If a patient develops certain severe side effects, the doctor may decide to delay or stop Dacogen treatment.

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How does Dacogen work?

The active substance in Dacogen, decitabine, is a cytidine deoxynucleoside analogue. This means that it is similar to cytidine deoxynucleoside, a fundamental component of the DNA (genetic material) of cells. In the body, decitabine is converted into decitabine triphosphate, which is then incorporated into the DNA where it blocks the activity of enzymes called DNA methyltransferases (DNMTs). These enzymes promote the development and progression of cancer. By blocking DNMTs, decitabine will prevent the increase of tumour cells and lead to their death.

How has Dacogen been studied?

Dacogen has been studied in one main study involving 485 adults, who were newly diagnosed with AML but were not eligible for standard induction chemotherapy. Dacogen was compared with either supportive care (any medicine or technique to help patients, excluding cancer medicines or surgery) or low-dose cytarabine (another cancer medicine). Treatment was given for as long as patients benefited from it. The main measure of effectiveness was how long the patients lived.

What benefit has Dacogen shown during the studies?

Patients receiving Dacogen lived for an average of 7.7 months compared with 5.0 months for patients receiving supportive care or treatment with cytarabine.

What is the risk associated with Dacogen?

The most common side effects with Dacogen (seen in more than 35% of patients) are fever, anaemia (low red blood cell count) and thrombocytopenia (low blood platelet count). The most common serious side effects (seen in more than 20% of patients) include pneumonia (lung infection), thrombocytopenia, neutropenia (low blood count of neutrophils, a type of white blood cell), febrile neutropenia (low white blood cell count with fever) and anaemia.

Dacogen must not be used in people who are breastfeeding. As it is not known whether the active substance is excreted in breast milk, in the event that a patient is breastfeeding, they must discontinue breastfeeding if they require treatment with Dacogen.

For the full list of all restrictions and side effects reported with Dacogen, see the package leaflet.

Why has Dacogen been approved?

The CHMP noted that the improvement in survival with Dacogen in patients with AML was modest but relevant, as the benefits of current treatments are limited in patients who are not eligible for standard induction chemotherapy. There were no major safety concerns with Dacogen and the overall safety profile was similar to that of low-dose cytarabine but some side effects such as infections and neutropenia were more common with Dacogen. The CHMP decided that Dacogen's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Dacogen

The European Commission granted a marketing authorisation valid throughout the European Union for Dacogen on 20 September 2012.

The full EPAR for Dacogen can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Dacogen, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Dacogen can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 06-2016.