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Ivozall (*clofarabine*)

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

What is Ivozall and what is it used for?

Ivozall is a cancer medicine that is used to treat children and adults up to 21 years of age who have acute lymphoblastic leukaemia (ALL), a cancer of the lymphocytes (a type of white blood cell). It is used when the disease has not responded to, or has come back (relapsed) after at least two other treatments and when no other treatment is expected to work.

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

How is Ivozall used?

Ivozall can only be obtained with a prescription. Treatment should be started and supervised by a doctor who has experience in the management of patients with acute leukaemias. It is available as a solution for infusion (drip) into a vein.

The recommended dose of Ivozall is based on the patient's height and weight. It is given by infusion lasting 2 hours every day for five days. This cycle of treatment should be repeated every 2 to 6 weeks. Doctors should review treatment in patients whose condition does not improve after one or two treatment cycles.

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

How does Ivozall work?

The active substance in Ivozall, clofarabine, is a cytotoxic agent (a medicine that kills cells that are dividing, such as cancer cells). It belongs to the group of cancer medicines called 'antimetabolites'. Clofarabine is an 'analogue' of adenine, one of the building blocks of the genetic material of cells (DNA and RNA). This means that clofarabine resembles adenine and by taking adenine's place in the body, it interferes with the action of enzymes involved in making genetic material, called 'DNA polymerase' and 'RNA reductase'. This stops the cells making new DNA and RNA and from dividing, thereby slowing down the growth of cancer cells.

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How has Ivozall been studied?

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

As for every medicine, the company provided studies on the quality of Ivozall. There was no need for 'bioequivalence' studies to investigate whether Ivozall is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Ivozall is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Ivozall?

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

Why is Ivozall authorised in the EU?

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

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

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

Other information about Ivozall

Ivozall received a marketing authorisation valid throughout the EU on 14 November 2019.

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

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