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EPAR summary for the public

Evoltra

clofarabine

This is a summary of the European public assessment report (EPAR) for Evoltra. 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 Evoltra.

What is Evoltra?

Evoltra is a cancer medicine that contains the active substance clofarabine. It is available as a concentrate that is made up into a solution for infusion (drip) into a vein.

What is Evoltra used for?

Evoltra is used to treat children and adults up to 21 years of age who have acute lymphoblastic leukaemia (ALL), which is 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.

Because the number of patients with ALL is low, the disease is considered 'rare', and Evoltra was designated an 'orphan medicine' (a medicine used in rare diseases) on 5 February 2002.

The medicine can only be obtained with a prescription.

How is Evoltra used?

Evoltra treatment should be started and supervised by a doctor who has experience in the management of patients with acute leukaemias. The recommended dose is 52 mg per square metre of body surface area (calculated using the patient's height and weight). It is given by infusion lasting two hours every day for five days. The treatment should be repeated every two to six weeks. Most patients who respond to treatment do so after one or two treatment cycles.

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For further information see the package leaflet.

How does Evoltra work?

The active substance in Evoltra, clofarabine, is a cytotoxic (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, which is part of the fundamental genetic material of cells (DNA and RNA). This means that clofarabine takes the place of adenine in the body, and interferes with the enzymes involved in making genetic material, called 'DNA polymerase' and 'RNA reductase'. This stops the cells making new DNA and RNA, and slows down the growth of tumour cells.

How has Evoltra been studied?

Evoltra has been examined in one study of 61 patients below 21 years of age with ALL. All of the patients had previously received at least two other types of treatment but were not eligible for any other treatment. The average age of the treated patients was 12 years. The main measure of effectiveness was the number of patients who went into 'remission' (clearance of leukaemia from the bone marrow and complete or partial recovery of blood cell counts to normal levels). The study did not compare Evoltra with any other treatments.

What benefit has Evoltra shown during the studies?

In the main study, 20% of the patients went into remission (12 out of 61). Overall, the patients in the study survived for an average of 66 weeks.

After treatment with Evoltra, 10 patients were able to go on to have a stem cell transplant. This is a complex procedure where the patient receives stem cells from a matched donor to help restore the bone marrow. Stem cells are cells that can develop into different types of cell.

What is the risk associated with Evoltra?

The most common side effects with Evoltra (seen in more than 1 patient in 10) were febrile neutropenia (low white blood cell counts with fever), anxiety, headache, flushing (reddening of the face), vomiting, diarrhoea, nausea (feeling sick), palmar-plantar erythrodysaesthesia syndrome (rash and numbness on the palms and soles), pruritus (itching), pyrexia (fever), mucosal inflammation (inflammation of the moist body surfaces, such as the lining of the mouth) and fatigue (tiredness). For the full list of all side effects reported with Evoltra, see the package leaflet.

Evoltra must not be given to patients with severe kidney or liver disease. Breast-feeding should be stopped before, during and after treatment with Evoltra. For the full list of restrictions, see the package leaflet.

Why has Evoltra been approved?

Patients with ALL who have not responded to or who have relapsed after receiving at least two treatments have a very poor chance of survival. The CHMP concluded that Evoltra treatment may provide a way of obtaining remission, and of facilitating a stem cell transplant. The Committee decided that Evoltra's benefits are greater than its risks and recommended that it be given marketing authorisation.

Evoltra has been authorised under 'exceptional circumstances'. This means that, because the disease is rare, it has not been possible to obtain complete information about Evoltra. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Evoltra?

The company that makes Evoltra will set up a registry to monitor the medicine's side effects.

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

A risk management plan has been developed to ensure that Evoltra is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Evoltra, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Evoltra

The European Commission granted a marketing authorisation valid throughout the European Union for Evoltra on 29 May 2006.

The full EPAR for Evoltra 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 Evoltra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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

This summary was last updated in 12-2015.