



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/299783/2012
EMA/H/C/002055

EPAR summary for the public

Pixuvri

pixantrone

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

What is Pixuvri?

Pixuvri is a medicine that contains the active substance pixantrone. It is available as a powder that is made up into a solution for infusion (a drip into a vein).

What is Pixuvri used for?

Pixuvri is used to treat adult patients with non-Hodgkin's B cell lymphoma. This is a cancer of the lymph tissue (part of the immune system) that affects a type of white blood cell called B lymphocytes, or B cells. Pixuvri is used when the lymphoma is aggressive and has come back or has not responded to other chemotherapy treatments (medicines to treat cancer).

The medicine can only be obtained with a prescription.

How is Pixuvri used?

Pixuvri must be given by a doctor who has experience in the use of anticancer medicines and who has access to facilities for monitoring the patient.

The dose of Pixuvri is based on the patient's body surface area (calculated using the patient's height and weight). The recommended dose is 50 mg/m² given as an infusion into a vein over at least 60 minutes on days 1, 8 and 15 of a 28-day cycle. Pixuvri can be given for up to six cycles. In patients who develop side effects or who have very low blood levels of neutrophils (a type of white blood cell



that fights infection) and platelets (components that help the blood to clot), the dose may have to be reduced or treatment may have to be delayed.

How does Pixuvri work?

The active substance in Pixuvri, pixantrone, is a cytotoxic medicine (a medicine that kills cells that are dividing, such as cancer cells) that belongs to the group 'anthracyclines'. It works by interfering with the DNA within cells, preventing them from making more copies of DNA and making proteins. This means that the cancer cells in non-Hodgkin's B cell lymphoma cannot divide and eventually die.

How has Pixuvri been studied?

The effects of Pixuvri were first tested in experimental models before being studied in humans.

Pixuvri was compared with other chemotherapy treatments in one main study involving 140 adults with aggressive non-Hodgkin's B cell lymphoma, who had previously received at least two other treatments, and whose cancer had come back or had not responded to treatment. Patients were given either six cycles of Pixuvri or another approved anticancer medicine chosen by their doctor.

The main measure of effectiveness was the number patients who had a complete response to treatment.

What benefit has Pixuvri shown during the studies?

Pixuvri was shown to be beneficial in patients with aggressive non-Hodgkin's B cell lymphoma: 20% of patients responded completely to Pixuvri (14 out of 70 patients) compared with 5.7% of patients receiving other agents (4 out of 70 patients).

What is the risk associated with Pixuvri?

The most common side effects with Pixuvri (seen in more than 1 patient in 10) are neutropenia, leucopenia and lymphopenia (low levels of different types of white blood cells), thrombocytopenia (low levels of platelets in the blood), anaemia (low levels of red blood cells), nausea (feeling sick), vomiting, skin discolouration, hair loss, chromaturia (abnormal colouration of the urine) and asthenia (weakness). For the full list of all side effects reported with Pixuvri, see the package leaflet.

Pixuvri must not be used in patients who are hypersensitive (allergic) to pixantrone or any of the other ingredients. It must not be used in patients with severe liver problems and in patients whose bone marrow produces abnormally low levels of blood cells. Patients receiving Pixuvri must not be given vaccines containing attenuated (weakened live) viruses.

Why has Pixuvri been approved?

The CHMP concluded that patients with aggressive non-Hodgkin's B cell lymphoma had a better response to treatment with Pixuvri than other cancer treatments. In addition, patients treated with Pixuvri lived for longer without their disease getting worse. The CHMP also considered the seriousness of the disease and the lack of suitable alternative treatments for patients whose non-Hodgkin's B cell lymphoma has come back or has not responded to other chemotherapy treatments. The side effects of the medicine were considered to be short term and manageable. However, the Committee noted that more data were needed on the benefits of Pixuvri in patients who have received previous treatment with rituximab (another medicine commonly used to treat lymphoma). The CHMP concluded that the benefits of Pixuvri are greater than its risks and recommended that it be given marketing authorisation.

Pixuvri has been given 'conditional approval'. This means that there is more evidence to come about the medicine, in particular its benefits in patients who have previously been treated with rituximab. 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 Pixuvri?

The company that makes Pixuvri will carry out a study to further investigate the effects of using Pixuvri in patients who had received prior treatment with rituximab.

Other information about Pixuvri

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Pixuvri on 10 May 2012.

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

This summary was last updated in 03-2012.