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Vyxeos (*daunorubicin / cytarabine*)

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

What is Vyxeos and what is it used for?

Vyxeos is a cancer medicine used to treat adults with newly diagnosed acute myeloid leukaemia, a cancer of white blood cells. Vyxeos is used when the leukaemia was caused by previous treatments (e.g. for other cancers) or is associated with certain changes in the bone marrow known as myelodysplasia.

The active substances in Vyxeos are daunorubicin and cytarabine.

How is Vyxeos used?

Vyxeos is given by infusion (drip) into a vein. The dose is calculated based on the patient's height and weight; the infusion is given over 90 minutes on days 1, 3 and 5 of an initial treatment course; if the disease responds and the doctor considers further courses would be of benefit, Vyxeos is given on days 1 and 3 of each further course. The doctor may delay doses or stop treatment if the patient has severe side effects.

Vyxeos can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in using cancer medicines. For more information about using Vyxeos, see the package leaflet or contact your doctor or pharmacist.

How does Vyxeos work?

The active substances in Vyxeos, cytarabine and daunorubicin, have been used together to treat leukaemia and other types of cancer for many years. They interfere in different ways with the production of new DNA within cells, which means the cells are unable to grow and multiply, and they eventually die.

In this medicine, cytarabine and daunorubicin are contained in tiny fat droplets called 'liposomes'. The liposomes are expected to remain in the patient's body for longer than conventional cytarabine and daunorubicin medicines and to build up in the patient's bone marrow. The liposomes protect the cancer medicines from being broken down early, which is expected to enhance their effect on cancer cells.

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What benefits of Vyxeos have been shown in studies?

Vyxeos has been shown to improve how long patients lived in one main study involving 309 patients with high-risk acute myeloid leukaemia linked to previous treatment or associated with myelodysplasia. The study compared Vyxeos with conventional cytarabine and daunorubicin infusions.

Patients given Vyxeos lived on average around 9.6 months after treatment, whereas those given conventional cytarabine and daunorubicin lived about 6 months.

Some 34% of patients given Vyxeos (52 of 153) were able to go on to have a stem cell transplant (a potentially curative procedure where the patient's bone marrow is replaced by stem cells to form new, healthy bone marrow) compared with 25% (39 of 156) given conventional treatment.

What are the risks associated with Vyxeos?

The most common side effects with Vyxeos (which may affect more than 1 in 5 people) are hypersensitivity (allergic reactions, especially rash), febrile neutropenia (low white cell counts with fever), oedema (swelling), diarrhoea, colitis (inflamed bowel), mucositis (inflammation of the moist body surfaces), tiredness, muscle and bone pain, belly pain, decreased appetite, cough, headache, chills, arrhythmias (irregular heart rhythm), fever, sleep disorders and hypotension (low blood pressure).

For the full list of side effects and restrictions with Vyxeos, see the package leaflet.

Why is Vyxeos authorised in the EU?

Vyxeos improved survival compared with conventional cytarabine and daunorubicin in patients with acute myeloid leukaemia who have a poor prognosis and few alternatives. The side effects were similar to the known side effects of the active substances and were considered manageable. The European Medicines Agency decided that Vyxeos's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Vyxeos

Vyxeos received a marketing authorisation valid throughout the EU on 23 August 2018.

Further information on Vyxeos can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 10-2018.