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Vyxeos liposomal[1] (*daunorubicin / cytarabine*)

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

What is Vyxeos liposomal and what is it used for?

Vyxeos liposomal is a cancer medicine used to treat adults with newly diagnosed acute myeloid leukaemia, a cancer of white blood cells. It 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 liposomal are daunorubicin and cytarabine.

How is Vyxeos liposomal used?

Vyxeos liposomal is given by infusion (drip) into a vein over 90 minutes and the dose is calculated using the patient's height and weight. It is given on days 1, 3 and 5 of the first treatment course. If the medicine works well enough and the doctor considers further courses would be of benefit, Vyxeos liposomal 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 liposomal 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 liposomal, see the package leaflet or contact your doctor or pharmacist.

How does Vyxeos liposomal work?

The active substances in Vyxeos liposomal, daunorubicin and cytarabine, 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, daunorubicin and cytarabine are contained in tiny fat droplets called 'liposomes'. The liposomes are expected to remain in the patient's body for longer than conventional daunorubicin and cytarabine 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.

[1] Previously known as Vyxeos.

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What benefits of Vyxeos liposomal have been shown in studies?

Vyxeos liposomal 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 liposomal with conventional daunorubicin and cytarabine infusions.

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

Some 34% of patients given Vyxeos liposomal (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 liposomal?

The most common side effects with Vyxeos liposomal (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 liposomal, see the package leaflet.

Why is Vyxeos liposomal authorised in the EU?

Vyxeos liposomal improved survival compared with conventional daunorubicin and cytarabine 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 liposomal'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 liposomal?

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

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

Other information about Vyxeos liposomal

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

Further information on Vyxeos liposomal can be found on the Agency's website: ema.europa.eu/medicines/human/epar/vyxeos-liposomal.

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