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Celdoxome pegylated liposomal (*doxorubicin*)

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

What is Celdoxome pegylated liposomal and what is it used for?

Celdoxome pegylated liposomal is a medicine used to treat the following types of cancer in adults:

- metastatic breast cancer in patients at risk of heart problems. 'Metastatic' means the cancer has spread to other parts of the body. Celdoxome pegylated liposomal is used on its own for this disease;
- advanced ovarian cancer in women whose previous treatment including a platinum-based cancer medicine has stopped working;
- Kaposi's sarcoma in patients with AIDS who have very damaged immune system. Kaposi's sarcoma is a cancer that causes abnormal tissue to grow under the skin, on moist body surfaces or on internal organs;
- multiple myeloma (a cancer of the cells in the bone marrow), in patients with progressive disease who have received at least one previous treatment and have already had a bone marrow transplantation or are unsuitable for it. Celdoxome pegylated liposomal is used in combination with bortezomib (another cancer medicine).

Celdoxome pegylated liposomal contains the active substance doxorubicin.

Celdoxome pegylated liposomal is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but in Celdoxome pegylated liposomal the active substance is enclosed in 'pegylated liposomes' (tiny fat particles coated with a substance called polyethylene glycol) while this is not the case for the reference medicine. The reference medicine for Celdoxome pegylated liposomal is Adriamycin.

How is Celdoxome pegylated liposomal used?

Celdoxome pegylated liposomal can only be obtained with a prescription. It should only be given under the supervision of a doctor who is qualified in the use of cytotoxic (cell-killing) cancer medicines. It cannot be interchanged with other medicines that contain doxorubicin.

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Celdoxome pegylated liposomal is given as an infusion (drip) into a vein. The dose depends on the condition it is used for and the patient's liver function, and is calculated on the basis of the patient's weight and height. The duration of treatment depends on the condition being treated. The doctor may stop treatment or reduce the dose if certain side effects occur.

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

How does Celdoxome pegylated liposomal work?

Doxorubicin, the active substance in Celdoxome pegylated liposomal, is a cytotoxic medicine that belongs to a group of medicines called 'anthracyclines'. It interferes with the DNA in cancer cells, preventing them from making more copies of DNA and making proteins. This means that cancer cells cannot divide and eventually die. Celdoxome pegylated liposomal builds up in areas in the body where the blood vessels have an abnormal shape, such as within tumours, where the medicine's action is concentrated.

Doxorubicin has been available since the 1960s. In Celdoxome pegylated liposomal, it is enclosed in 'pegylated liposomes' (tiny fat particles coated with a substance called polyethylene glycol). This slows down removal of the medicine, allowing it to circulate in the blood for longer. It also reduces its effects on healthy tissues and cells, so it is less likely to cause some side effects.

What benefits of Celdoxome pegylated liposomal have been shown in studies?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Adriamycin, and do not all need to be repeated for Celdoxome pegylated liposomal. However, since Adriamycin contains doxorubicin in a different form (not enclosed in pegylated liposomes), the company also presented results from a study in patients with metastatic breast cancer to show that Celdoxome pegylated liposomal is bioequivalent to Caelyx pegylated liposomal, another authorised medicine that contains doxorubicin in pegylated liposomal form. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the risks associated with Celdoxome pegylated liposomal?

The most common side effects with Celdoxome pegylated liposomal (which may affect more than 1 in 5 people) are neutropenia (low levels of neutrophils, a type of white blood cell), nausea (feeling sick), leucopenia (low levels of white blood cells), anaemia (low levels of red blood cells) and tiredness.

The most common serious side effects (which may occur in more than 1 in 50 people) are neutropenia, leucopenia, lymphopenia (low levels of lymphocytes, a type of white blood cell), anaemia, thrombocytopenia (low levels of blood platelets), palmar-plantar erythrodysaesthesia syndrome (hand-foot syndrome; rash and numbness on the palms and soles), stomatitis (inflammation of the lining of the mouth), tiredness, diarrhoea, vomiting, nausea, fever, dyspnoea (difficulty breathing), and pneumonia (infection of the lungs).

Celdoxome pegylated liposomal must not be used to treat Kaposi's sarcoma that could be treated effectively with 'local' treatments that only affect the site of the tumour or with alfa interferon treatment that affects the whole body. Celdoxome pegylated liposomal must not be used in people allergic to peanut or soya.

For the full list of side effects and restrictions of Celdoxome pegylated liposomal, see the package leaflet.

Why is Celdoxome pegylated liposomal authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Celdoxome pegylated liposomal has been shown to be comparable to the reference medicine Adriamycin and bioequivalent to Caelyx pegylated liposomal. Therefore, the Agency decided that the benefits of Celdoxome pegylated liposomal 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 Celdoxome pegylated liposomal?

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

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

Other information about Celdoxome pegylated liposomal

Celdoxome pegylated liposomal received a marketing authorisation valid throughout the EU on 15 September 2022

Further information on Celdoxome pegylated liposomal can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Celdoxome-pegylated-liposomal.

This overview was last updated in 10-2022.