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Zolsketil pegylated liposomal (*doxorubicin*)

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

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

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

- breast cancer that has spread to other parts of the body in patients at risk of heart problems. Zolsketil 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;
- multiple myeloma (a cancer of the white blood cells in the bone marrow), in patients with progressive disease who have received at least one other treatment in the past and have already had, or are unsuitable for, a bone marrow transplantation. Zolsketil pegylated liposomal is used in combination with bortezomib (another cancer medicine);
- Kaposi's sarcoma in patients with AIDS who have a 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.

Zolsketil pegylated liposomal contains the active substance doxorubicin and is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance called Adriamycin. However, in Zolsketil pegylated liposomal the active substance is enclosed in tiny fatty spheres called liposomes, whereas this is not the case for Adriamycin.

How is Zolsketil pegylated liposomal used?

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

Zolsketil pegylated liposomal is given by infusion (drip) into a vein. The dose depends on the condition it is used for and is calculated on the basis of the patient's weight and height. The doctor may stop treatment or reduce the dose if certain side effects occur or if the patient has liver problems.

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

How does Zolsketil pegylated liposomal work?

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

Doxorubicin has been available since the 1960s. In Zolsketil 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 specific side effects.

What benefits of Zolsketil 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 Zolsketil 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 ovarian cancer to show that Zolsketil pegylated liposomal is bioequivalent to Caelyx, 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 Zolsketil pegylated liposomal?

The most common side effects with Zolsketil 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), leukopenia (low levels of leukocytes, a type of white blood cell), anaemia (low levels of red blood cells), and tiredness.

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

Zolsketil pegylated liposomal must not be used to treat Kaposi's sarcoma that can be treated effectively with 'local' treatments that only affect the site of the tumour or with alfa interferons.

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

Why is Zolsketil pegylated liposomal authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Zolsketil pegylated liposomal has been shown to be comparable to the reference medicine and bioequivalent to Caelyx. Therefore, the Agency's view was that the benefits of Zolsketil pegylated liposomal outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Zolsketil pegylated liposomal?

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

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

Other information about Zolsketil pegylated liposomal

Zolsketil pegylated liposomal received a marketing authorisation valid throughout the EU on 31 May 2022.

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

This overview was last updated in 05-2022.