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Lextemy (*bevacizumab*)

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

What is Lextemy and what is it used for?

Lextemy is a cancer medicine that is used to treat adults with the following cancers:

- cancer of the colon (large bowel) or the rectum, when it has spread to other parts of the body;
- breast cancer that has spread to other parts of the body;
- a type of lung cancer called non-small cell lung cancer when it is advanced or has spread or come back, and cannot be treated with surgery. Lextemy can be used in non-small cell lung cancer unless the cancer originates in cells called squamous cells;
- cancer of the kidney (renal cell carcinoma) that is advanced or has spread elsewhere;
- cancer of the ovary or associated structures (the fallopian tube that carries the egg from the ovary to the womb, and the peritoneum, the membrane that lines the abdomen) when the cancer is advanced;
- cancer of the cervix (the neck of the womb) that has persisted or come back after treatment, or has spread to other parts of the body.

Lextemy is used in combination with other cancer medicines, depending on the nature of any previous treatments or the presence of mutations (genetic changes) in the cancer that affect how well particular medicines work.

Lextemy is a 'biosimilar medicine'. This means that Lextemy is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Lextemy is Avastin. For more information on biosimilar medicines, see here.

Lextemy contains the active substance bevacizumab.

How is Lextemy used?

Lextemy can only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the use of cancer medicines.

Lextemy is given by infusion (drip) into a vein. The first infusion of Lextemy should last 90 minutes, but subsequent infusions may be given more quickly if side effects with the earlier infusion were

acceptable. The dose depends on the patient's weight, the type of cancer being treated and the other cancer medicines being used. Treatment is continued for as long as the patient benefits from it. The doctor may interrupt or stop treatment if the patient develops certain side effects.

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

How does Lextemy work?

The active substance in Lextemy, bevacizumab, is a monoclonal antibody (a type of protein) that has been designed to attach to vascular endothelial growth factor (VEGF), a protein that circulates in the blood and makes new blood vessels grow. By attaching to VEGF, Lextemy stops its effect. As a result, the cancer cannot develop its own blood supply and cancer cells are starved of oxygen and nutrients, helping to slow down the growth of tumours.

What benefits of Lextemy have been shown in studies?

Laboratory studies comparing Lextemy with Avastin have shown that the active substance in Lextemy is highly similar to that in Avastin in terms of structure, purity and biological activity. Studies have also shown that giving Lextemy produces similar levels of the active substance in the body to giving Avastin.

In addition, a study involving 671 patients with advanced non-small cell lung cancer showed that Lextemy was as effective as Avastin when given with the cancer medicines paclitaxel and carboplatin. After 18 weeks the cancer had responded to treatment in 42% of those given Lextemy and 43% of those given Avastin, which was considered comparable.

Because Lextemy is a biosimilar medicine, the studies on effectiveness and safety of bevacizumab carried out with Avastin do not all need to be repeated for Lextemy.

What are the risks associated with Lextemy?

The safety of Lextemy has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Avastin.

The most common side effects with bevacizumab (which may affect more than 1 in 10 people) are hypertension (high blood pressure), tiredness or asthenia (weakness), diarrhoea and abdominal (belly) pain. The most serious side effects are gastrointestinal perforation (hole in the gut wall), haemorrhage (bleeding) and arterial thromboembolism (blood clots in the arteries). For the full list of all side effects reported with Lextemy, see the package leaflet.

Lextemy must not be used in people who are hypersensitive (allergic) to bevacizumab or any of the other ingredients, to Chinese hamster ovary cell products or other recombinant (genetically engineered) antibodies. It must not be given to pregnant women.

Why is Lextemy authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Lextemy has a highly similar structure, purity and biological activity to Avastin and is distributed in the body in the same way. In addition, studies in non-small cell lung cancer have shown that the safety and effectiveness of Lextemy is equivalent to that of Avastin in this indication.

All these data were considered sufficient to conclude that Lextemy will behave in the same way as Avastin in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Avastin, the benefits of Lextemy 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 Lextemy?

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

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

Other information about Lextemy

Lextemy received a marketing authorisation valid throughout the EU on 21 April 2021.

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

This overview was last updated in 04-2021.