EMA/623814/2022
EMEA/H/C/005534

Vegzelma (*bevacizumab*)

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

What is Vegzelma and what is it used for?

Vegzelma is a cancer medicine used to treat adults with the following types of cancer, in combination with other cancer medicines:

- cancer of the colon (large intestine) or rectum that is metastatic (has spread to other parts of the body), in combination with chemotherapy medicines that include a 'fluoropyrimidine';
- metastatic breast cancer, in combination with paclitaxel or capecitabine;
- advanced non-small cell lung cancer in patients whose cancer cells are not mainly of the squamous type, where it is given with platinum-based chemotherapy;
- advanced non-small cell lung cancer in patients whose cancer cells have a certain change ('activating mutations') in the gene for a protein called EGFR, where it is given in combination with erlotinib;
- advanced or metastatic kidney cancer, in combination with interferon alfa-2a;
- epithelial cancer of the ovary, cancer of the fallopian tube (that connect the ovaries to the womb) or the peritoneum (the membrane lining the abdomen). Vegzelma is used in combination with certain chemotherapy medicines in newly diagnosed patients when the cancer is advanced, or in previously treated patients whose cancer has come back (recurrent);
- cancer of the cervix (the neck of the womb) that is persistent, recurrent or metastatic. Vegzelma is given in combination with paclitaxel and either the platinum-based medicine cisplatin or, if this cannot be used, another chemotherapy medicine, topotecan.

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

Vegzelma contains the active substance bevacizumab.

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How is Vegzelma used?

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

Vegzelma is available as a concentrate that is made up into a solution for infusion (drip) into a vein. The first infusion of Vegzelma should last 90 minutes, but subsequent infusions may be given more quickly if the first infusion is tolerated well. The dose is between 5 and 15 mg per kilogram body weight every two or three weeks, depending on the type of cancer being treated. The treatment is continued until the patient no longer benefits from it. The doctor may decide to interrupt or stop treatment if the patient develops certain side effects. For more information about using Vegzelma, see the package leaflet or contact your doctor or pharmacist.

How does Vegzelma work?

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

What benefits of Vegzelma have been shown in studies?

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

In addition, a main study of 689 patients with non-small cell lung cancer that had come back or spread to other parts of the body showed that Vegzelma was as effective as Avastin in treating the cancer. Around 42% of patients given Vegzelma or Avastin responded to treatment.

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

What are the risks associated with Vegzelma?

The safety of Vegzelma 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 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 Vegzelma, see the package leaflet.

Vegzelma 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 antibodies. It must not be given to pregnant women.

Why is Vegzelma authorised in the EU?

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

All these data were considered sufficient to conclude that Vegzelma 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 Vegzelma 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 Vegzelma?

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

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

Other information about Vegzelma

Vegzelma received a marketing authorisation valid throughout the EU on 17 August 2022.

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

This overview was last updated in 08-2022.