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Avzivi (*bevacizumab*)

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

What is Avzivi and what is it used for?

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

- cancer of the colon or rectum (parts of the large intestine) 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, metastatic or recurrent (cancer that has come back) non-small cell lung cancer that cannot be removed by surgery, in patients whose cancer cells are not mainly of the squamous type, where it is given with platinum-based chemotherapy;
- advanced, metastatic or recurrent non-small cell lung cancer that cannot be removed by surgery, 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). Avzivi 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;
- cancer of the cervix (the neck of the womb) that is persistent, recurrent or metastatic. Avzivi is given in combination with paclitaxel and either platinum-based medicine cisplatin or, if it cannot be used, another chemotherapy medicine, topotecan.

Avzivi contains the active substance bevacizumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Avzivi is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Avzivi is Avastin. For more information on biosimilar medicines, see here.

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How is Avzivi used?

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

Avzivi is given as an infusion (drip) into a vein. The first infusion of Avzivi should last 90 minutes, but subsequent infusions may be given more quickly if the first infusion is well tolerated. Avzivi is given 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 also decide to interrupt or stop treatment if the patient develops certain side effects.

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

How does Avzivi work?

The active substance in Avzivi, 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 develop. By attaching to VEGF, Avzivi stops it having an effect. This reduces the blood supply that keeps cancer cells growing and helps to reduce the growth and spread of the cancer.

What benefits of Avzivi have been shown in studies?

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

In addition, Avzivi was shown to be as effective as Avastin in a main study involving 651 patients with advanced non-squamous non-small cell lung cancer who also received chemotherapy. After 18 weeks of treatment, about 48% of patients who received Avzivi had either a complete (no sign of cancer) or a partial (shrinking of the cancer) response to treatment, compared with about 45% of patients who received Avastin.

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

What are the risks associated with Avzivi?

The safety of Avzivi 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.

For the complete list of side effects and restrictions with Avzivi, see the package leaflet.

The most common side effects with bevacizumab (which may affect more than 1 in 10 people) include hypertension (high blood pressure), tiredness or asthenia (weakness), diarrhoea and abdominal (belly) pain.

The most serious side effects with bevacizumab (which may affect up to 1 in 10 people) include gastrointestinal perforation (hole in the gut wall), haemorrhage (bleeding) and arterial thromboembolism (blood clot in the arteries).

Avzivi 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 Avzivi authorised in the EU?

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

All these data were considered sufficient to conclude that Avzivi will have the same effects as Avastin in its authorised uses. Therefore, the Agency's view was that, as for Avastin, the benefits of Avzivi 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 Avzivi?

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

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

Other information about Avzivi

Avzivi received a marketing authorisation valid throughout the EU on 26 July 2024.

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

This overview was last updated in 07-2024.