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Abevmy (*bevacizumab*)

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

What is Abevmy and what is it used for?

Abevmy 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. Abevmy 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) that is advanced or has come back after treatment;
- 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.

Abevmy 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.

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

Abevmy contains the active substance bevacizumab.

How is Abevmy used?

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

Abevmy is given by infusion (drip) into a vein. The first infusion of Abevmy 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 Abevmy, see the package leaflet or contact your doctor or pharmacist.

How does Abevmy work?

The active substance in Abevmy, 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, Abevmy 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 Abevmy have been shown in studies?

Laboratory studies comparing Abevmy with Avastin have shown that the active substance in Abevmy is highly similar to that in Avastin in terms of structure, purity and biological activity. Studies have also shown that giving Abevmy 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 Abevmy 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 Abevmy and 43% of those given Avastin, which was considered comparable.

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

What are the risks associated with Abevmy?

The safety of Abevmy 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 Abevmy, see the package leaflet.

Abevmy 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 Abevmy authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Abevmy 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 Abevmy is equivalent to that of Avastin in this indication.

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

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

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

Other information about Abevmy

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

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

This overview was last updated in 07-2021.