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Equidacent (*bevacizumab*)

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

What is Equidacent and what is it used for?

Equidacent 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. Equidacent can be used in non-small cell lung cancer unless it originates in cells of a particular type (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 spread to other parts of the body.

Equidacent 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.

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

Equidacent contains the active substance bevacizumab.

How is Equidacent used?

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

Equidacent is given by infusion (drip) into a vein. The first infusion of Equidacent should last 90 minutes, but subsequent infusions may be given more quickly if the first infusion has not caused

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

unacceptable side effects. 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 decide to interrupt or stop treatment if the patient develops certain side effects.

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

How does Equidacent work?

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

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

In addition, a study involving 731 patients with advanced non-small cell lung cancer showed that Equidacent was as effective as Avastin when given with the cancer medicines paclitaxel and carboplatin. After around 12 months, the cancer had responded to treatment in 52% of those given Equidacent and 53% of those given Avastin.

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

What are the risks associated with Equidacent?

The safety of Equidacent 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 Equidacent, see the package leaflet.

Equidacent 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 Equidacent authorised in the EU?

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

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

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

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

Other information about Equidacent

Equidacent received a marketing authorisation valid throughout the EU on 24 September 2020.

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

This overview was last updated in 09-2020.