EMA/3108/2020
EMEA/H/C/004728

Mvasi

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

What is Mvasi and what is it used for?

Mvasi 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. Mvasi can be used in non-small cell lung cancer unless it orginates 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 or the peritoneum, the membrane that lines the abdomen);
- 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.

Mvasi 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 its sensitivity to particular medicines.

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

How is Mvasi used?

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

Mvasi is available as a concentrate that is made up into a solution for infusion (drip) into a vein. The first infusion of Mvasi 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 and the other cancer medicines

being used. 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 further information, see the package leaflet.

How does Mvasi work?

The active substance in Mvasi, 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, Mvasi stops it having an 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 Mvasi have been shown in studies?

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

In addition, a study involving 642 patients with advanced non-small cell lung cancer showed that Mvasi was as effective as Avastin when given with the cancer medicines carboplatin and paclitaxel. The cancer responded to treatment in 39% of those given Mvasi (128 of 328 patients) and 42% of those given Avastin (131 of 314).

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

What are the risks associated with Mvasi?

The safety of Mvasi 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 Mvasi, see the package leaflet.

Mvasi 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 Mvasi authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Mvasi 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 Mvasi is equivalent to that of Avastin in this indication. All these data were considered sufficient to conclude that Mvasi 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 Mvasi 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 Mvasi?

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

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

Other information about Mvasi

Mvasi received a marketing authorisation valid throughout the EU on 15 January 2018.

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

This overview was last updated in 01-2020.