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Ogivri (*trastuzumab*)

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

What is Ogivri and what is it used for?

Ogivri is a cancer medicine used to treat the following conditions:

- early breast cancer (when the cancer has spread within the breast or to the lymph nodes ('glands') under the arm but not to other parts of the body) after surgery, chemotherapy (medicines to treat cancer), and radiotherapy (treatment with radiation) if applicable. It can also be used earlier in treatment, in combination with chemotherapy. For cancers that are locally advanced (including those that are inflammatory) or more than 2 cm wide, Ogivri is used before surgery in combination with chemotherapy and then again after surgery on its own;
- metastatic breast cancer (cancer that has spread to other parts of the body). It is used on its own when other treatments have not worked or are not suitable. It is also used in combination with other cancer medicines: with paclitaxel or docetaxel, or with another type of medicine called an aromatase inhibitor;
- metastatic gastric (stomach) cancer, in combination with cisplatin and either capecitabine or fluorouracil (other cancer medicines).

Ogivri can only be used when the cancer 'overexpresses HER2': this means that the cancer produces a protein called HER2 in large quantities on the cancer cells. HER2 is overexpressed in about a quarter of breast cancers and a fifth of gastric cancers.

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

Ogivri contains the active substance trastuzumab.

How is Ogivri used?

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

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It is given by infusion (drip) into a vein over 90 minutes every week or every 3 weeks for breast cancer, and every 3 weeks for gastric cancer. For early breast cancer, treatment is given for a year or until the disease comes back, and for metastatic breast or gastric cancer, treatment is continued for as long as it remains effective. The dose depends on the patient's body weight, on the condition being treated and on whether Ogivri is given every week or every 3 weeks.

The infusion may cause allergic reactions, so the patient should be monitored during and after the infusion for signs such as fever and chills. Patients who do not have significant reactions to the first 90-minute infusion can receive subsequent infusions over 30 minutes.

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

How does Ogivri work?

The active substance in Ogivri, trastuzumab, is a monoclonal antibody (a type of protein) designed to recognise and attach to the HER2 protein. By attaching to HER2, trastuzumab activates cells of the immune system, which then kill the tumour cells. Trastuzumab also stops HER2 from producing signals that cause the tumour cells to grow.

What benefits of Ogivri have been shown in studies?

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

In addition, one study involving 500 patients with metastatic breast cancer that overexpressed HER2 showed that Ogivri was effective in treating the condition. Patients received Ogivri or the reference medicine Herceptin, together with other cancer medicines (paclitaxel or docetaxel). A response to treatment after 24 weeks was seen in 70% of the patients given Ogivri (160 of 230) and 64% of the patients given Herceptin (146 of 228). In the light of all the data provided the difference was not assessed to be relevant and it was concluded that Ogivri would behave in the same way as Herceptin in its approved indications.

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

What are the risks associated with Ogivri?

The safety of Ogivri 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 Herceptin. The most common or serious side effects with Ogivri are heart problems, reactions related to the infusion, reduced levels of blood cells (especially white blood cells), infections and lung problems.

Ogivri can cause cardiotoxicity (harm to the heart), including heart failure (when the heart does not work as well as it should). Care should be taken if it is given to patients who already have heart problems or high blood pressure, and all patients need to be monitored during and after treatment to check their heart.

Ogivri must not be used in people who are hypersensitive (allergic) to trastuzumab, mouse proteins or to any of the other ingredients. It must not be used in patients whose advanced cancer causes serious breathing problems even when resting, or who need oxygen therapy.

For the full list of side effects and restrictions, see the package leaflet.

Why is Ogivri authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ogivri has a highly similar structure, purity and biological activity to Herceptin and is distributed in the body in the same way. In addition, studies in metastatic breast cancer that overexpressed HER2 have shown that the effectiveness of Ogivri infusion is equivalent to that of Herceptin infusion.

All these data were considered sufficient to conclude that Ogivri will behave in the same way as intravenous Herceptin in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Herceptin, the benefit of Ogivri outweighs 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 Ogivri?

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

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

Other information about Ogivri

Ogivri received a marketing authorisation valid throughout the EU on 12 December 2018.

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

This overview was last updated in 12-2018.