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Vyloy (*zolbetuximab*)

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

What is Vyloy and what is it used for?

Vyloy is a cancer medicine that is used to treat adults with gastric or gastro-oesophageal junction adenocarcinoma (a type of cancer of the stomach or the transition between the stomach and oesophagus).

It is used in combination with chemotherapy when the cancer is locally advanced (has spread nearby) and cannot be removed by surgery or when it is metastatic (has spread to other parts of the body). Vyloy can be used when the cancer cells are HER2 negative and Claudin (CLDN) 18.2 positive; this means they do not have large quantities of the HER2 receptor (target) on their surface but do have a large number of the CLDN18.2 protein.

Gastric and gastro-oesophageal adenocarcinoma are rare, and Vyloy was designated an 'orphan medicine' (a medicine used in rare diseases) on 26 November 2010. Further information on the orphan designation can be found on the EMA website.

Vyloy contains the active substance zolbetuximab.

How is Vyloy used?

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer treatments.

The medicine is given as an infusion (drip) into a vein over a period of at least 2 hours. It is given every 2 or 3 weeks. Patients will be given medicines to prevent nausea (feeling sick) and vomiting before each infusion. Treatment can be continued for as long as it remains effective or until side effects become unacceptable.

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

How does Vyloy work?

The active substance in Vyloy, zolbetuximab, is a monoclonal antibody (a type of protein) that has been designed to attach to a protein called CLDN18.2, which is involved in keeping the cells of the stomach lining tightly attached to each other. When these cells become cancerous, the CLDN18.2 proteins are exposed, which allows zolbetuximab to attach to the cancer cells. The immune system

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(the body's natural defences) is then able to attack and kill the cancer cells, slowing down the progress of the disease.

What benefits of Vyloy have been shown in studies?

The benefits of Vyloy were investigated in two main studies in people with locally advanced or metastatic gastric or gastro-oesophageal junction cancer that was CLDN18.2 positive and HER2 negative.

In one study, 565 patients were given Vyloy or placebo (a dummy treatment), both in combination with mFOLFOX-6 (a combination of chemotherapy medicines). After starting treatment, patients on Vyloy lived, on average, for 11 months without their disease getting worse and 18.2 months overall. In patients given placebo, this was 8.9 months and 15.6 months.

In a second main study, 507 patients were given Vyloy or placebo, both in combination with oxaliplatin and capecitabine (chemotherapy medicines). Patients on Vyloy lived, on average, for 8.2 months without their disease getting worse and 14.3 months overall, compared with 6.8 months and 12.2 months in those given placebo.

What are the risks associated with Vyloy?

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

The most common adverse reactions with Vyloy (which may affect more than 1 in 10 people) include nausea, vomiting, decreased appetite, neutropenia (low levels of neutrophils, a type of white blood cell that fights infections), decreased neutrophil counts, weight loss, fever, hypoalbuminaemia (low levels of albumin, a blood protein), and peripheral oedema (swelling, especially of the ankles and feet). Other side effects (which may affect up to 1 in 10 people) include hypertension (high blood pressure), dyspepsia (indigestion), chills, salivary hypersecretion (excess production of saliva), infusion-related reactions and hypersensitivity (allergic reactions).

The most common serious side effects with Vyloy (which may affect up to 1 in 10 people) include vomiting, nausea and decreased appetite.

Why is Vyloy authorised in the EU?

Vyloy, together with standard chemotherapy, was shown to slow down worsening of the disease and increase survival time in people with advanced gastric or gastro-oesophageal junction adenocarcinoma. Side effects resulting from the addition of Vyloy to standard chemotherapy were considered acceptable; they were mainly gastrointestinal (such as nausea and vomiting) and mostly occurred at the start of treatment. The European Medicines Agency therefore decided that Vyloy's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Vyloy?

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

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

Other information about Vyloy

Vyloy received a marketing authorisation valid throughout the EU on 19 September 2024.

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

This overview was last updated in 09-2024.