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Gazyvaro *(obinutuzumab)*

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

What is Gazyvaro and what is it used for?

Gazyvaro is a cancer medicine used to treat adults with:

- previously untreated chronic lymphocytic leukaemia (CLL). CLL is a cancer of B-lymphocytes, a type of white blood cell. Gazyvaro is used together with chlorambucil (another cancer medicine) in patients for whom the cancer medicine fludarabine is not recommended;
- follicular lymphoma (FL), another type of cancer of B-lymphocytes. Gazyvaro is used together with chemotherapy (other cancer medicines) in patients who have not had previous treatment for advanced FL. It is also used with the medicine bendamustine in patients whose disease has not responded to treatment involving the medicine rituximab or whose cancer has progressed within 6 months after such treatment. Once the disease has responded to treatment, Gazyvaro is then used on its own for the maintenance treatment of FL.

Gazyvaro contains the active substance obinutuzumab.

These diseases are rare, and Gazyvaro was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the European Medicines Agency's website (CLL: 10 October 2012; FL: 19 June 2015).

How is Gazyvaro used?

Gazyvaro can only be obtained with a prescription and treatment should be given under the close supervision of an experienced doctor. As serious side effects including allergic reactions can develop, treatment should be given in facilities where these reactions can be treated promptly.

Gazyvaro is given by infusion (drip) into a vein over several hours. It is given in six or eight cycles and each cycle lasts 21 or 28 days.

The dosage schedule depends on what Gazyvaro is used for.

Patients may also be given other medicines to prevent infusion-related reactions and other side effects. For more information about using Gazyvaro, see the package leaflet or contact your doctor or pharmacist.

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How does Gazyvaro work?

The active substance in Gazyvaro, obinutuzumab, is a monoclonal antibody (a type of protein) that has been designed to attach to the protein CD20, which is found on B-lymphocytes. In CLL and FL, cancerous B-lymphocytes multiply too quickly and replace normal cells in the bone marrow (where blood cells are made) and in lymph nodes. By attaching to CD20 on B-lymphocytes, obinutuzumab makes them a target for the body's immune (defence) system, which kills the B-lymphocytes.

What benefits of Gazyvaro have been shown in studies?

CLL

In CLL, Gazyvaro delayed the disease getting worse in previously untreated patients who had other medical conditions and were therefore ineligible for fludarabine-based therapy. In one main study involving 781 patients, those treated with Gazyvaro and chlorambucil lived longer without their disease getting worse than patients treated with chlorambucil alone (26.7 months on average versus 11.1 months). Similarly, patients treated with Gazyvaro and chlorambucil lived longer without their disease getting worse than patients treated with rituximab and chlorambucil (26.7 months versus 15.2 months).

FL

Gazyvaro was of benefit in one main study involving 1,202 patients with previously untreated FL. The study compared Gazyvaro plus other chemotherapy medicines with rituximab plus other chemotherapy medicines. Over a follow-up period of about 3 years on average, 17% (101 of 601 patients) given Gazyvaro died or their disease got worse, compared with 24% (144 of 601 patients) given rituximab.

Gazyvaro has also been investigated in a study involving 321 patients with FL in whom treatment with rituximab had either not worked or had stopped working. Patients treated with Gazyvaro and bendamustine lived longer without their disease getting worse than patients treated with bendamustine alone (29.2 months on average versus 13.7 months).

What are the risks associated with Gazyvaro?

The most common side effects with Gazyvaro (which may affect more than 1 in 10 people) are upper respiratory infections (such as throat and nose infections), pneumonia (lung infection), urinary tract infections, inflammation in the nose and throat, sinusitis (inflammation of the sinuses), shingles, coughs, diarrhoea, constipation, joint and back pain, pain in arms and legs, headache, insomnia, hair loss, itching, fever, weakness, tiredness, neutropenia and leucopenia (low white blood cell counts), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts) and reactions related to the infusion (which may include vomiting, dizziness, breathing difficulties, flushing, changes in blood pressure and rapid heart rate). For the full list of side effects and restrictions of Gazyvaro, see the package leaflet.

Why is Gazyvaro authorised in the EU?

The European Medicines Agency decided that Gazyvaro's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that the benefit of Gazyvaro in prolonging the survival of CLL and FL patients before their disease worsened was clearly demonstrated. The pattern of side effects was considered acceptable in the light of the medicine's benefit.

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

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

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

Other information about Gazyvaro

Gazyvaro received a marketing authorisation valid throughout the EU on 23 July 2014.

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

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