EMA/524799/2017
EMEA/H/C/001131

EPAR summary for the public

Arzerra

ofatumumab

Medicinal product no longer authorised

This is a summary of the European Public Assessment Report (EPAR) for Arzerra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use of Arzerra.

For practical information about using Arzerra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Arzerra and what is it used for?

Arzerra is a cancer medicine used to treat adults with chronic lymphocytic leukaemia (CLL), a cancer of a type of white blood cells called lymphocytes. It is used:

- in previously untreated patients who cannot be treated with fludarabine; in these patients it is used together with chlorambucil or bendamustine (other cancer medicines);
- in patients whose disease has not responded to previous treatment (known as refractory disease) with fludarabine and a medicine called alemtuzumab;
- in patients whose disease has come back after previous treatment (known as relapsed disease). In these patients Arzerra is used together with fludarabine and cyclophosphamide.

Arzerra contains the active substance ofatumumab.

Because the number of patients with CLL is low, the disease is considered ‘rare’, and Arzerra was designated an ‘orphan medicine’ (a medicine used in rare diseases) on 7 November 2008.

How is Arzerra used?

Arzerra can only be obtained with a prescription and should be given under the supervision of a doctor who has experience in treating cancer and in a place where facilities for resuscitating patients are readily available.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2017. Reproduction is authorised provided the source is acknowledged.

Arzerra is available as a concentrate that is made up into a solution for infusion (drip) into a vein. It is given using an infusion pump. The dosing schedule depends on whether the patient has been treated before and whether the patient's disease has come back.

Before each infusion, the patient receives medicines, such as a corticosteroid, an antihistamine and paracetamol, to help to prevent infusion reactions (such as rash, fever, allergic reactions and difficulty breathing). To reduce the risk of these reactions, infusions are started slowly (particularly when first starting treatment) and then speeded up every 30 minutes if no reactions occur. If reactions occur, treatment is interrupted and may be restarted at a slower rate when the patient has recovered or stopped permanently if a serious allergic reaction occurs. For more information on how Arzerra is used, see the summary of product characteristics (also part of the EPAR).

How does Arzerra work?

The active substance in Arzerra, ofatumumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) that is found in certain cells in the body. Ofatumumab has been designed to attach to a protein called CD20 that is found on the surface of lymphocytes, including the cancerous lymphocytes seen in CLL. By attaching to CD20, ofatumumab stimulates the body's immune system to attack the cancerous cells, helping to control the disease.

What benefits of Arzerra have been shown in studies?

Previously untreated CLL

One main study involving 447 previously untreated patients who could not be treated with fludarabine-based therapy compared a combination of Arzerra plus chlorambucil with chlorambucil given alone. Arzerra plus chlorambucil was effective at increasing progression-free survival (how long the patients lived without their disease getting worse), with patients living on average for 22.4 months without their disease getting worse, compared with 13.1 months in patients given chlorambucil alone.

Refractory CLL

Arzerra has been investigated in one main study involving 223 patients with CLL whose disease had not responded to previous treatment. In 95 of these patients, the disease had not responded to both fludarabine and alemtuzumab, and in 112, treatment with fludarabine had failed but the patients had not been treated with alemtuzumab because this medicine was not suitable for them. The remaining 16 patients did not fall into either group. Arzerra was not compared with any other treatments in this study. The main measure of effectiveness was the number of patients who 'responded' to treatment. The response to treatment was assessed by looking at the patients' symptoms, the number of lymphocytes in their blood, results of blood and bone marrow tests and the size of their lymph nodes, liver and spleen. In patients whose previous treatment with both fludarabine and alemtuzumab had failed, 49% (47 out of 95) responded to treatment with Arzerra. The response rate was slightly lower in patients whose treatment with fludarabine had failed but who were not suitable for treatment with alemtuzumab (43%).

Medicinal product no longer authorised

Relapsed CLL

One main study involving 365 patients whose cancer had come back compared the combination of Arzerra plus fludarabine and cyclophosphamide with fludarabine and cyclophosphamide used alone. Arzerra plus fludarabine and cyclophosphamide was effective at increasing progression-free survival, with patients living on average for 28.9 months without their disease getting worse, compared with 18.8 months in patients given fludarabine and cyclophosphamide alone.

What are the risks associated with Arzerra?

The most common side effects with Arzerra (seen in more than 1 patient in 10) are lower respiratory tract infection (infection of the lungs such as pneumonia), upper respiratory tract infection (nose and throat infection), neutropenia (low levels of neutrophils, a type of white blood cell), anaemia (low red blood cell counts), nausea (feeling sick), fever, rash, dyspnoea (difficulty breathing), cough, diarrhoea and tiredness.

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

Why is Arzerra approved?

The European Medicines Agency decided that the medicine's benefits are greater than its risks and recommended that it be given marketing authorisation. The Agency noted that Arzerra was shown to be effective at treating patients with CLL (previously untreated patients, patients who had not responded to previous treatment with fludarabine and alemtuzumab and patients whose cancer had come back after previous treatment). The Agency also noted that patients with CLL who had not responded to previous treatment have limited treatment options.

Arzerra was originally given 'conditional approval', because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

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

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

Other information about Arzerra

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Arzerra on 19 April 2010. This was switched to a full marketing authorisation on 24 April 2015.

The full EPAR for Arzerra can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Arzerra, read the Package Leaflet (also part of the EPAR).

The summary of the opinion of the Committee for Orphan Medicinal Products for Arzerra can also be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designations.

Medicinal product no longer authorised

This summary was last updated in 08-2017.

Medicinal product no longer authorised