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Enjaymo (*sutimlimab*)

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

What is Enjaymo and what is it used for?

Enjaymo is a medicine for treating haemolytic anaemia (excess breakdown of red blood cells) in adults with cold agglutinin disease (CAD).

CAD is a rare blood disorder where the immune system (the body's natural defence) recognises red blood cells as foreign and attacks them. This causes agglutination (clumping together) and haemolysis (disruption) of the red blood cells, resulting in low red blood cell counts and low levels of haemoglobin.

Haemolytic anaemia is rare, and Enjaymo was designated an 'orphan medicine' (a medicine used in rare diseases) on 17 February 2016. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3161609.

Enjaymo contains the active substance sutimlimab.

How is Enjaymo used?

The medicine can only be obtained with a prescription and treatment should be supervised by a doctor with experience in the management of patients with CAD. Before treatment, patients should have received specific vaccinations to reduce the risk of infections.

Enjaymo is given as an infusion (drip) into a vein lasting 1 or 2 hours. There are two dose levels recommended dependent on the patient's weight. The treatment is given once a week for the first 2 weeks and then every 2 weeks. Patients should be monitored during and after the infusion for certain side effects related to the infusion. Treatment should be stopped temporarily or permanently if the patient experiences certain side effects.

Patients receive Enjaymo for at least three months at a health care facility. If the infusion is well tolerated during this period, the doctor may consider home infusion. Home infusion is performed by a health care professional.

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

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How does Enjaymo work?

The active substance in Enjaymo, sutimlimab, is a monoclonal antibody (a type of protein) that attaches to an immune system protein, C1s, which is involved in attacking red blood cells of patients with CAD. By attaching to C1s, the medicine prevents the immune system from attacking the red blood cells, reducing the destruction of red blood cells and relieving symptoms of the disease.

What benefits of Enjaymo have been shown in studies?

Enjaymo has been shown to improve haemolytic anaemia in two main studies involving a total of 66 adults with CAD who had moderate to severe haemolytic anaemia.

In the first study, patients who had not recently received a blood transfusion were given Enjaymo or placebo (a dummy treatment). After treatment for 26 weeks, around 73% (16 of 22) of patients given Enjaymo compared with 15% (3 out of 20) of those given placebo had responded to treatment, as measured by an increase in haemoglobin level of at least 1.5 g per dL and no need for a blood transfusion or other CAD treatment.

The second study involved patients with CAD who had recently received a blood transfusion and who received Enjaymo for 26 weeks. The medicine was not compared with another treatment. The study found that 54% (13 out of 24) of patients responded to treatment, as measured by either an increase in haemoglobin level of at least 2 g per dL or reaching haemoglobin level of at least 12g per dl, and no need for a blood transfusion or other CAD treatment.

Response to treatment was retained throughout the treatment period for both studies but diminished rapidly following end of treatment.

Other measures also showed a reduced destruction of red blood cells and improvement of quality of life with Enjaymo.

What are the risks associated with Enjaymo?

The most common side effects with Enjaymo (which may affect more than 1 in 10 people) are headache, high blood pressure, urinary tract infection (infection of the structures that carry urine), upper respiratory tract infection (nose and throat infection), nasopharyngitis (inflammation of the nose and throat), nausea, abdominal pain, infusion-related reactions and cyanosis (bluish discoloration of hands and feet in response to cold and stress).

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

Why is Enjaymo authorised in the EU?

Enjaymo has been shown to improve haemolytic anaemia in patients with CAD by increasing haemoglobin levels. Since the side effects are considered manageable, the European Medicines Agency decided that Enjaymo's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Enjaymo will provide prescribers and patients with information on the need for vaccination before starting treatment and the risk of serious infections, including how to recognise signs and symptoms of infections.

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

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

Other information about Enjaymo

Enjaymo received a marketing authorisation valid throughout the EU on 15 November 2022.

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

This overview was last updated in 11-2022.