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Summary report on authorisation dated 20 June 2025

Enjaymo® (active substance: sutimlimab)

Authorisation in Switzerland: 21 June 2023

Solution for infusion for the treatment of haemolysis in adults with cold agglutinin disease (CAD)

About the medicinal product

Enjaymo contains the active substance sutimlimab and is used to treat haemolysis in adults with cold agglutinin disease (CAD).

CAD is a rare disease in which the immune system (the body's defence system) attacks and destroys red blood cells, which can cause anaemia (deficiency of red blood cells).

Since CAD is a rare and life-threatening disease, Enjaymo has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Mode of action

The active substance in Enjaymo, sutimlimab, is an antibody that inhibits a particular immune system reaction implicated in the destruction of the red blood cells. As a result, Enjaymo can inhibit the breakdown of red blood cells (haemolysis) and alleviate the symptoms of the disease.

Administration

Enjaymo is a prescription-only medicine.

It is available as a solution for infusion in the dosage strength of 50 mg of active substance per ml.

The recommended dosage is determined by the patient's body weight. The dose for patients weighing 39 kg to less than 75 kg is 6,500 mg, that for patients weighing 75 kg and over is 7,500 mg. For the first two weeks, Enjaymo is administered intravenously (into the veins) once a week. After that, administration is every two weeks. The infusions are administered under the supervision of healthcare professionals.

Efficacy

The efficacy and safety of Enjaymo were investigated in 2 studies, named CADENZA and CARDINAL.

Both were conducted with patients with cold agglutinin disease (CAD).

The CADENZA study compared the efficacy of Enjaymo with placebo (dummy drug) in symptomatic patients who had not received a blood transfusion within six months or who had not received more than one blood transfusion in the 12 months prior to study enrolment. Efficacy was measured in terms of the response rate, using three criteria: increase in haemoglobin level of at least 1.5 g/dl from baseline; patients did not require a blood transfusion between week 5 and week 26; and patients did not require treatment for their cold agglutinin disease.

The overall response rate for patients treated with Enjaymo was 72.7%, compared with just 15.0% for the placebo group.

The single-arm CARDINAL study investigated patients who had received a blood transfusion in the six months prior to enrolment. Efficacy was measured in terms of the response rate, using three criteria: increase in haemoglobin level of at least 2 g/dl from baseline or a haemoglobin level of at least 12 g/dl; patients did not require a blood transfusion between week 5 and week 26; and patients did not require treatment for their cold agglutinin disease.
Overall, 54% of the patients responded.

Precautions, undesirable effects, & risks

Enjaymo must not be used in those who are hypersensitive to the active substance or any of the excipients.

Patients who receive Enjaymo may have an increased susceptibility to serious infections. Accordingly, patients should be monitored for early signs of infection and receive immediate treatment if symptoms occur. Care should be taken if treatment is discontinued because the effects on haemolysis diminish. Thromboembolic[1] events have also been observed with Enjaymo.

The most frequent undesirable effects observed during treatment with Enjaymo are high blood pressure, urinary tract infections, respiratory tract infections, inflammation of the mucous membranes in the nasal cavity, headaches, abdominal pain and nausea.

Serious side effects such as cyanosis[2] were also reported, resulting in some patients discontinuing treatment.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Cold agglutinin disease (CAD) is a rare, serious condition that involves chronic haemolysis and anaemia. People with CAD are at greater risk of experiencing thromboembolic events and dying prematurely.

Before Enjaymo was authorised, there were no authorised treatments for CAD in Swit-

[1]Thromboembolic: "Thromboembolic" means that a blood clot (thrombus) is blocking a blood vessel (embolism)

[2] Cyanosis: Bluish or greyish discolouration of the skin caused by a lack of oxygen in the blood

zerland. Enjaymo, containing the active substance sutimlimab, provides a new treatment option by inhibiting haemolysis.

Taking all the risks and precautions into account, and based on the available data, the benefits of Enjaymo outweigh the risks. Swissmedic has therefore authorised the medicinal product Enjaymo, containing the active substance sutimlimab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals – Enjaymo®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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