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Saphnelo (*anifrolumab*)

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

What is Saphnelo and what is it used for?

Saphnelo is a medicine used as an add-on treatment in adults with systemic lupus erythematosus (SLE), a disease in which the immune system (the body's natural defences) attacks normal cells and tissues, causing inflammation and organ damage.

Saphnelo is given to patients who have antibodies against their own cells (autoantibodies) and whose disease is still moderate to severe despite standard treatment.

Saphnelo contains the active substance anifrolumab.

How is Saphnelo used?

Saphnelo can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of SLE.

Saphnelo is given as an infusion (drip) into a vein. The recommended dose is 300 mg given over 30 minutes every four weeks. The doctor may interrupt or stop treatment if the patient develops reactions linked to the infusion. Patients who have previously had such reactions may be given preventive medicines before treatment.

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

How does Saphnelo work?

In SLE, a protein called type I interferon (IFN) is involved in causing the immune system to attack normal cells and tissues. Type I IFN acts by attaching to a protein called type I IFN receptor.

The active substance in Saphnelo, anifrolumab, is a monoclonal antibody (another type of protein) designed to attach to this receptor, thereby preventing type I IFN from binding to it. This blocks the action of type I IFN and reduces the inflammation and organ damage that occur in SLE.

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What benefits of Saphnelo have been shown in studies?

Two main studies found that 300 mg of Saphnelo was more effective as an add-on to standard treatment than placebo (a dummy treatment) in reducing SLE disease activity, measured using a standard index known as BICLA. The studies involved a total of 822 adults with moderate to severe autoantibody-positive SLE who were treated with Saphnelo for one year.

In the first study, disease activity decreased in 47% of patients treated with Saphnelo compared with 30% of patients who were given placebo. In the second study, disease activity decreased in 48% of patients treated with Saphnelo compared with 32% of those who received placebo.

What are the risks associated with Saphnelo?

The most common side effects with Saphnelo (which may affect more than 1 in 10 people) are upper respiratory tract (nose and throat) infection and bronchitis (inflammation of the airways in the lungs).

The most common serious side effect (which may affect up to 1 in 100 people) is herpes zoster (shingles).

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

Why is Saphnelo authorised in the EU?

The European Medicines Agency considered that Saphnelo used as an add-on treatment provides a modest, but clinically meaningful reduction in disease activity in patients with SLE, for whom there is a high unmet need for new therapies. As the safety of the medicine is considered acceptable, the Agency concluded that Saphnelo'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 Saphnelo?

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

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

Other information about Saphnelo

Saphnelo received a marketing authorisation valid throughout the EU on 14 February 2022.

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

This overview was last updated in 02-2022.