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Saphnelo® (active substance: anifrolumab)

First authorisation in Switzerland: 31 August 2022

Infusion for the adjunctive therapy of systemic lupus erythematosus (SLE)

About the medicinal product

The medicinal product Saphnelo, containing the active substance anifrolumab, is used in adults with systemic lupus erythematosus (SLE) in addition to a standard treatment. SLE is commonly referred to simply as "lupus". It is a relapsing-remitting disease (autoimmune disease) in which the immune system, which defends the body against infection, attacks the body's own cells and tissues. This results in inflammation and organ damage. This autoimmune disease is incurable. Women are far more frequently affected than men (ratio of 9:1).

Mode of action

In SLE, a protein known as type I interferon (IFN) is involved in the inflammatory processes in the body. IFN acts by binding to another protein known as the type 1 IFN receptor.

Anifrolumab is a monoclonal antibody (immunologically active protein) which blocks this type 1 IFN binding site. The blockade can help to reduce inflammation in the body that triggers the symptoms of lupus, thereby reducing the risk of organ damage.

Use

Saphnelo, containing the active substance anifrolumab, is a prescription-only medicine. Treatment with Saphnelo should only be administered by a doctor with experience of treating SLE.

Saphnelo is a concentrate for solution for infusion available in the dosage strength 300 mg/2 ml. The concentrate is diluted with saline solution and administered via a vein over 30 minutes. Administration is repeated every 4 weeks.

Efficacy

The efficacy and safety of Saphnelo were investigated in two studies. Study 05/TULIP1 included 457 and study 04/TULIP2 365 patients with SLE. The results of study

MUSE/1013 involving 307 patients were used to support these studies.

The monitoring period was 52 weeks. During this period, 300 mg of anifrolumab or dummy drug (placebo) were administered in addition to the standard treatment every four weeks. The BICLA index was used to measure disease activity. In study 04/TULIP2, disease activity improved in 48% of patients who received Saphnelo compared to 32% who received placebo. In study 05/TULIP1, 47% of patients in the Saphnelo group saw an improvement in disease activity, compared with 30% in the placebo group.

Precautions, undesirable effects & risks

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

The most frequent undesirable effects, affecting more than one in ten patients, are infections of the upper airways (nose and throat) and bronchitis (inflammation of the airways leading to the lungs).

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

SLE is an incurable, chronic, life-threatening autoimmune disease. The studies showed a relevant effect on disease activity in SLE patients who received Saphnelo. Taking all the risks and precautions into account, the benefits of Saphnelo outweigh the risks. Swissmedic has therefore authorised the medicinal product Saphnelo, containing the active substance anifrolumab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals: Saphnelo®

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 Public Summary SwissPAR.

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