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Vyvgart (*efgartigimod alfa*)

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

What is Vyvgart and what is it used for?

Vyvgart is a medicine for treating adults with generalised myasthenia gravis (a disease that leads to muscle weakness and tiredness) and whose immune system produce antibodies against a protein called acetylcholine receptor, located on muscle cells. It is given together with other medicines used for the treatment of myasthenia gravis.

Myasthenia gravis is rare, and Vyvgart was designated an 'orphan medicine' on 21 March 2018.

Vyvgart contains the active substance efgartigimod alfa.

How is Vyvgart used?

Vyvgart can only be obtained with a prescription and treatment should be initiated by doctors with experience in the management of patients with neuromuscular disorders.

Vyvgart is available as a concentrate for solution to be administered as infusion (drip) into a vein. The dose of Vyvgart depends on the patient's weight and is given once a week over cycles of 4 weeks. The doctor will decide on how many cycles to give after considering how the patient responds to the treatment.

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

How does Vyvgart work?

For a muscle to contract, a substance called acetylcholine is released from a nerve and attaches to acetylcholine receptors on the muscle cells. In patients with generalised myasthenia gravis, the immune system produces autoantibodies (proteins that attack parts of a person's own body by mistake) that damage these receptors. Because of this damage, the muscles are not able to contract as well as normal, leading to muscle weakness and difficulty moving.

Vyvgart works by attaching to and blocking the action of a protein called neonatal Fc receptor (FcRn) which is involved in regulating the levels of antibodies in the blood. By blocking FcRn, Vyvgart decreases the level of autoantibodies thereby improving the ability of muscles to contract and reducing the symptoms of the disease and their impact on daily activities.

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What benefits of Vyvgart have been shown in studies?

A study involving 129 patients with myasthenia gravis who had anti-acetylcholine receptor autoantibodies showed that Vyvgart was effective at improving symptoms of the disease. The study looked at the effect of treatment using a Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) scale which measures the impact of the disease on patients' daily activities. The scale ranges from 0 to 24 and higher scores indicate more severe symptoms.

After 6.5 months, about 68% of patients treated with Vyvgart had a reduction of at least 2 points in their MG-ADL scores compared with about 30% of the patients treated with placebo (a dummy treatment).

What are the risks associated with Vyvgart?

The most common side effects with Vyvgart, which may affect around 1 in 10 people, are upper respiratory tract infections (infections of the nose and throat) and urinary tract infection (infection of the parts of the body that collect and pass out urine).

For the full list of side effects of Vyvgart, see the package leaflet.

Why is Vyvgart authorised in the EU?

The main study showed that patients treated with Vyvgart have less severe symptoms as measured by a decrease in their MG-ADL scores.

The most common side effects were upper respiratory tract infections and urinary tract infections but serious side effects causing patients to stop treatment were rare.

The European Medicines Agency therefore decided that Vyvgart'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 Vyvgart?

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

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

Other information about Vyvgart

Vyvgart received a marketing authorisation valid throughout the EU on 10 August 2022.

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

This overview was last updated in 08-2022.