EMA/181244/2025
EMEA/H/C/005849

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 (the body's defence system) produce antibodies against a protein called acetylcholine receptor, found on muscle cells. It is given together with other medicines used for the treatment of myasthenia gravis;
- chronic inflammatory demyelinating polyneuropathy (CIDP), a disease in which the immune system works abnormally and destroys the protective covering around the nerves. It is used in patients whose disease is worsening or came back and who have had previous treatment with corticosteroids or immunoglobulins (other medicines used to treat CIDP).

Myasthenia gravis and CIDP are rare, and Vyvgart was designated an 'orphan medicine' for these diseases on 21 March 2018 and 14 January 2022, respectively.

Vyvgart contains the active substance efgartigimod alfa.

How is Vyvgart used?

Vyvgart can only be obtained with a prescription and treatment should be started by a doctor experienced in the management of patients with neuromuscular disorders (disorders affecting muscle function).

For patients with myasthenia gravis, Vyvgart is given as an infusion (drip) into a vein or by injection under the skin. It is given once a week over a 4-week cycle. The doctor will decide on how many cycles to give depending on the response to treatment.

For patients with CIDP, Vyvgart is given by injection under the skin once a week. The doctor may decide to give treatment every other week depending on the response to treatment.

Patients receiving Vyvgart as an injection, or their care provider, may inject the medicine themselves after the first 4 injections for CIDP or 5 injections for myasthenia gravis and appropriate training.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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.

In patients with CIDP, the immune system produces autoantibodies that damage the protective covering of the nerves, leading to neuromuscular problems such as muscle weakness and numbness.

The active substance in Vyvgart, efgartigimod alfa, works by attaching to and blocking the action of a protein called neonatal Fc receptor (FcRn) which helps control the levels of antibodies in the blood. By blocking FcRn, Vyvgart reduces the level of autoantibodies, which protects both the acetylcholine receptors on muscle cells and the nerve coverings, thereby reducing the symptoms of generalised myasthenia gravis and CIDP.

What benefits of Vyvgart have been shown in studies?

Generalised myasthenia gravis

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 the first treatment cycle, 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).

Chronic inflammatory demyelinating polyneuropathy

Another study involved patients with CIDP. The first part of the study involved 322 patients with CIDP and looked at whether patients responded to treatment with Vyvgart within a maximum of 12 weeks of treatment. Response to treatment was defined as evidence of clinical improvement, as assessed by the adjusted inflammatory neuropathy cause and treatment (INCAT) score, inflammatory Rasch-built overall disability scale and grip strength. Response to treatment was achieved in around 67% (214 out of 322) of the patients. This part of the study did not compare Vyvgart with another medicine or placebo.

The second part of the study involved 221 patients with CIDP who had responded to treatment with Vyvgart in the first part of the study described above and looked at the effectiveness of Vyvgart at preventing CIDP from coming back (relapse) compared with placebo. Relapse was defined as a worsening of the adjusted INCAT score and occurred in 28% (31 out of 111) of patients receiving Vyvgart compared with 54% (59 out of 110) of those given placebo.

What are the risks associated with Vyvgart?

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

The most common side effects with Vyvgart (which may affect more than 1 in 10 people) include reactions at the site of injection, such as rash, itching and pain, and upper respiratory tract infections (infections of the nose and throat). Other common side effects (which may affect up to 1 in 10 people) include urinary tract infection (infection of the parts of the body that collect and pass out urine).

Why is Vyvgart authorised in the EU?

Vyvgart was shown to be effective in treating adults with myasthenia gravis and CIDP, with a manageable safety profile.

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 05-2025.