EMA/509663/2023
EMEA/H/C/005450

Zilbrysq (*zilucoplan*)

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

What is Zilbrysq and what is it used for?

Zilbrysq is a medicine used to treat generalised myasthenia gravis (a disease that leads to muscle weakness and tiredness) in adults whose immune system produces antibodies against a protein called the acetylcholine receptor. It is given together with other medicines used for treating myasthenia gravis.

Zilbrysq contains the active substance zilucoplan.

How is Zilbrysq used?

The medicine can only be obtained with a prescription. Treatment with Zilbrysq should be supervised by healthcare professionals experienced in managing patients with neuromuscular disorders (disorders that affect the nerves that control muscles).

Zilbrysq is given as an injection under the skin once daily. The dose depends on the patient's body weight. The patient or their carer can give the injection if they have been trained appropriately.

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

How does Zilbrysq work?

The active substance in Zilbrysq, zilucoplan, is designed to attach to the C5 complement protein, which is part of the immune system called the 'complement system'.

Myasthenia gravis is caused by the production of autoantibodies (proteins that attack parts of a person's own body by mistake) that damage acetylcholine receptors, which in normal conditions allow signals from the nerves to trigger muscle contractions. The attachment of autoantibodies to acetylcholine receptors activates the complement system, which leads to damage of the contact point between the nerve and muscle. Due to this damage, the muscles are not able to contract as well as normal, leading to muscle weakness and difficulty moving. By attaching to the C5 complement protein, zilucoplan reduces the activity of the complement system, which decreases the damage of acetylcholine receptors thereby improving the symptoms of the disease.

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

What benefits of Zilbrysq have been shown in studies?

A study involving 174 adults with generalised myasthenia gravis and anti-acetylcholine receptor autoantibodies showed that Zilbrysq was more effective than placebo (a dummy treatment) at improving symptoms of the disease.

The effect of treatment was measured using the Myasthenia Gravis – Activities of Daily Living (MG-ADL) scale, a scoring system for assessing the impact of the disease on a patient's daily life. A reduction in a patient's MG-ADL score means that there has been an improvement in their disease symptoms.

The study showed that after 12 weeks of treatment, patients given Zilbrysq had a reduction of about 4.4 points in the MG-ADL score compared to a reduction of 2.3 points in those given placebo.

What are the risks associated with Zilbrysq?

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

The most common side effects with Zilbrysq (which may affect more than 1 in 10 people) include injection site reactions, such as bruising and pain, and upper respiratory tract (nose and throat) infections.

Due to an increased risk of developing meningococcal infection caused by the bacterium *Neisseria meningitidis,* Zilbrysq must not be given to patients who have an ongoing meningococcal infection. It should not be used in patients who have not been vaccinated against this bacterium at least two weeks before starting treatment. If treatment is started within two weeks of vaccination, patients should take appropriate antibiotics for two weeks after vaccination.

Why is Zilbrysq authorised in the EU?

Zilbrysq was shown to improve the symptoms of generalised myasthenia gravis in patients with anti-acetylcholine receptor autoantibodies. Given that patients can inject the medicine themselves, it provides an accessible treatment option for the disease. Although side effects with Zilbrysq were generally mild to moderate, there are some uncertainties about the medicine's long-term safety, given that the studies included a small number of patients for a relatively short period of time.

The European Medicines Agency therefore decided that Zilbrysq'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 Zilbrysq?

The company that markets Zilbrysq will ensure that patients can only access the medicine if their prescribers have made a written declaration of their vaccination against meningococcal disease. The company will also send reminders to prescribers to check if re-vaccination is needed for patients taking Zilbrysq and provide healthcare professionals and patients with safety information on the risk of meningococcal infections with the medicine. Patients will also be given an alert card that explains the symptoms of meningococcal infection and when to seek immediate medical care.

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

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

Other information about Zilbrysq

Zilbrysq received a marketing authorisation valid throughout the EU on 1 December 2023.

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

This overview was last updated in 12-2023.