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Rystiggo (*rozanolixizumab*)

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

What is Rystiggo and what is it used for?

Rystiggo is a medicine for treating adults with generalised myasthenia gravis (a disease that leads to muscle weakness and tiredness) and whose immune system produces antibodies against proteins called acetylcholine receptor or muscle-specific tyrosine kinase, which are found on muscle cells. It is given together with other medicines used for the treatment of myasthenia gravis.

Myasthenia gravis is rare, and Rystiggo was designated an 'orphan medicine' on 22 April 2020.

Rystiggo contains the active substance rozanolixizumab.

How is Rystiggo used?

Rystiggo can only be obtained with a prescription and treatment must be started and supervised by specialist healthcare professionals experienced in the management of neuromuscular or neuroinflammatory (involving inflammation of the nervous system) disorders.

Rystiggo is given as an infusion (drip) under the skin once a week for a cycle of 6 weeks. The doctor will decide how many cycles a patient needs and how often these should take place. The dose depends on the person's weight.

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

How does Rystiggo work?

In myasthenia gravis, an immune system protein called IgG antibody triggers the immune system to damage acetylcholine receptors or muscle-specific tyrosine kinase. The active substance in Rystiggo, rozanolixizumab, is a monoclonal antibody (a type of protein) designed to attach to FcRn, a protein that keeps IgG antibodies in the body for longer. By binding to and blocking FcRn, the medicine increases the removal of IgG antibodies, thereby preventing them from attacking the acetylcholine receptors or muscle-specific tyrosine kinase. This is expected to lead to an improvement in muscle function.

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What benefits of Rystiggo have been shown in studies?

A main study has shown that Rystiggo was effective in the treatment of adults with myasthenia gravis.

The study involved 200 adults with moderate to severe myasthenia gravis who had antibodies against acetylcholine receptor or muscle-specific tyrosine kinase and who received either Rystiggo at one of two doses (a low dose and a higher dose) or placebo (a dummy treatment). 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 one 6-week treatment cycle, patients treated with Rystiggo at either dose had a reduction of around 3.4 points in their MG-ADL scores compared with around 0.8 points for patients treated with placebo.

What are the risks associated with Rystiggo?

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

The most common side effects with Rystiggo (which may affect more than 1 in 10 people) include headache, diarrhoea and fever.

Why is Rystiggo authorised in the EU?

People with myasthenia gravis have few treatment options and the unmet medical need is particularly great for people with antibodies against muscle-specific tyrosine kinase.

Rystiggo has been shown to be effective in reducing the symptoms of myasthenia gravis, as measured by a reduction in the MG-ADL scores. Although the number of people in the study who had antibodies against muscle-specific tyrosine kinase was small, the results also suggested a benefit for these people. The European Medicines Agency noted that the main study only looked at the effect of the medicine after a single 6-week treatment cycle and did not assess the need for further treatment with Rystiggo should symptoms worsen. The company will therefore provide further data from a study looking at the use of Rystiggo in chronic (long-term) treatment.

In people who received the lower dose of Rystiggo, the safety profile was considered manageable and this was chosen as the recommended dose.

The Agency therefore decided that Rystiggo'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 Rystiggo?

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

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

Other information about Rystiggo

Rystiggo received a marketing authorisation valid throughout the EU on 5 January 2024.

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

This overview was last updated in 01-2024.