



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/818399/2017
EMA/H/C/002202

EPAR summary for the public

Gilenya

fingolimod

This is a summary of the European public assessment report (EPAR) for Gilenya. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Gilenya.

For practical information about using Gilenya, patients should read the package leaflet or contact their doctor or pharmacist.

What is Gilenya and what is it used for?

Gilenya is a type of medicine known as a 'disease-modifying therapy' that is used to treat adults with highly active relapsing-remitting multiple sclerosis (MS), a disease of the nerves in which inflammation destroys the protective sheath surrounding the nerve cells. 'Relapsing-remitting' means that the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions). Gilenya is used when the disease remains active despite appropriate treatment with at least one other disease-modifying therapy, or is severe and getting worse rapidly.

Gilenya contains the active substance fingolimod.

How is Gilenya used?

Gilenya can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in multiple sclerosis. Gilenya is available as capsules (0.5 mg), and the recommended dose is one capsule taken once a day by mouth.

Because Gilenya decreases the heart rate and can affect the heart's electrical activity and rhythm, the patient's blood pressure and heart activity is checked before treatment and after starting treatment, and also if Gilenya treatment is restarted after an interruption. Details on the recommendations for monitoring patients are found in the summary of product characteristics (SmPC).



How does Gilenya work?

In multiple sclerosis, the immune system (the body's defences) incorrectly attacks the protective sheath around the nerves in the brain and spinal cord. The active substance in Gilenya, fingolimod, prevents T cells (a type of white blood cell involved in the immune system) travelling from the lymph nodes towards the brain and spinal cord, thus limiting the damage they cause in multiple sclerosis. It does this by blocking the action of a receptor (target) on the T cells called the sphingosine-1-phosphate receptor, which is involved in controlling the movement of these cells in the body.

What benefits of Gilenya have been shown in studies?

Three main studies have found that Gilenya was more effective than placebo (a dummy treatment) and interferon beta-1a (another medicine for treating multiple sclerosis) in patients with relapsing-remitting multiple sclerosis. The main measure of effectiveness in all the studies was based on the number of relapses the patients experienced each year.

In two studies involving a total of 2,355 patients, Gilenya was compared with placebo over two years. Patients treated with Gilenya had around half the number of relapses compared with relapses in patients given placebo.

In the third study involving 1,292 patients, Gilenya was compared with interferon beta-1a over one year. Patients receiving Gilenya had around half the number of relapses compared with patients given interferon beta-1a.

What are the risks associated with Gilenya?

The most common side effects with Gilenya (seen in more than 1 patient in 10) are flu, sinusitis (inflammation of the sinuses), headache, cough, diarrhoea, back pain and raised liver enzyme levels (a sign of liver problems). The most serious side effects are infections, macular oedema (swelling in the central part of the retina at the back of the eye) and atrioventricular block (a type of heart rhythm disorder) at the start of treatment. For the full list of side effects with Gilenya, see the package leaflet.

Gilenya must not be used in patients at risk of infections due to a weakened immune system, patients with a severe infection or a long-term active infection such as hepatitis, patients with cancer or severe liver problems. Gilenya must also not be used in patients with certain diseases affecting the heart and blood vessels or in those who have had such diseases or problems with the blood supply to the brain. Women should not become pregnant while taking Gilenya and for two months after treatment has stopped. For the full list of restrictions with Gilenya, see the package leaflet.

Why is Gilenya approved?

The European Medicines Agency concluded that there is clear evidence of the benefit of Gilenya in relapsing-remitting multiple sclerosis and noted that it had the benefit of being taken by mouth. However, because of its safety profile, the Agency concluded that Gilenya should only be used in patients who have a real need for the medicine either because their disease has not improved with at least one other disease-modifying therapy or because it is severe and getting worse rapidly. In addition, the Agency concluded that all patients should have their heart activity closely monitored after the first dose. The Agency decided that Gilenya's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Gilenya?

The company that markets Gilenya will carry out a study to assess the risk of side effects on the heart and circulation. It must also ensure that all doctors who prescribe Gilenya receive an information pack containing important safety information, including a checklist of the risks with Gilenya and the situations where its use is not recommended. The checklist includes information on the tests and monitoring in patients before and after starting or when restarting treatment with Gilenya. The pack will also include information on the registry to collect data on babies born to women treated with Gilenya, as well as a patient reminder card with key safety information.

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

Other information about Gilenya

The European Commission granted a marketing authorisation valid throughout the European Union for Gilenya on 17 March 2011.

The full EPAR for Gilenya can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Gilenya, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2018.