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EPAR summary for the public

Gilenya

fingolimod

This is a summary of the European public assessment report (EPAR) for Gilenya. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Gilenya.

What is Gilenya?

Gilenya is a medicine that contains the active substance fingolimod. It is available as capsules (0.5 mg).

What is Gilenya used for?

Gilenya is a type of medicine known as a 'disease-modifying therapy' that is used to treat adults with highly active multiple sclerosis (MS). MS is a disease of the nerves, in which inflammation destroys the protective sheath surrounding the nerve cells. Gilenya is used in the type of MS known as 'relapsing-remitting', when the patient has attacks (relapses) in between periods with decreased symptoms (remissions). It 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.

The medicine can only be obtained with a prescription.

How is Gilenya used?

Treatment with Gilenya should be started and supervised by a physician experienced in MS. The recommended dose is one capsule taken once a day by mouth.

Because Gilenya decreases the heart rate, doctors should check the patient's blood pressure, heart rate, as well as their heart by electrocardiogram (ECG, a test that measures the electrical activity of the heart) before giving the first dose. After the first dose, the patient's blood pressure and heart rate should be checked every hour for six hours. In addition, doctors may perform ECG continuously during



six hours or extend the monitoring period if needed. The same monitoring required for the first dose will sometimes be needed when 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 MS, the body's immune system malfunctions and attacks parts of the central nervous system (the brain and spinal cord). The active substance in Gilenya, fingolimod, reduces the ability of T cells (a type of white blood cell involved in the immune system) to move from the lymph nodes towards the brain and spinal cord thus limiting the damage they cause in MS. It does this by blocking the action of a receptor on the T cells called the sphingosine-1-phosphate receptor, which is involved in regulating the movement of these cells in the body.

How has Gilenya been studied?

Gilenya at two doses (0.5 mg and 1.25 mg) has been investigated in three main studies in MS patients. In two studies, Gilenya was compared with placebo (a dummy treatment) over two years in 2,355 patients with relapsing-remitting MS. In the third study, Gilenya was compared with beta-interferon over one year in 1,292 patients. The main measure of effectiveness in all the studies was based on the number of relapses the patients experienced each year.

What benefit has Gilenya shown during the studies?

Gilenya was shown to be more effective than placebo and beta-interferon in reducing the number of relapses. The lower dose of Gilenya was shown to be as effective as the higher dose. In the first two studies, the number of relapses per year among patients treated with Gilenya was around half the number seen in patients given placebo. In the third study, the number of relapses in patients receiving Gilenya was also around half the number seen in patients given beta-interferon.

What is the risk associated with Gilenya?

The most common side effects with Gilenya (seen in more than 1 patient in 10) are flu infections, sinusitis (inflammation of the sinuses), headache, cough, diarrhoea, back pain and raised liver enzyme levels. The most serious side effects are infections, macular oedema (swelling in the macula, the central part of the retina at the back of the eye) and transient atrioventricular block (a type of heart rhythm disorder) at the start of treatment. For the full list of all side effects reported 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 active infection or a long-term active infection such as hepatitis, cancer or severe liver problems. Women should avoid becoming pregnant while taking Gilenya and for two months after treatment has stopped.

Gilenya is known to cause lowering of the heart rate at the beginning of treatment. Therefore, Gilenya is not recommended in people taking certain antiarrhythmic medicines (medicines used to restore normal cardiac rhythm) and in patients taking certain medicines that lower the heart rate. Gilenya is also not recommended in patients with certain cardiovascular disease or a history of cardiovascular or cerebrovascular disease (problems with the blood supply to the brain). For the full list of restrictions, see the package leaflet.

Why has Gilenya been approved?

The CHMP concluded that there is clear evidence of the benefit of Gilenya in relapsing-remitting MS and noted that it had the benefit of being taken by mouth. However, because of its safety profile, the Committee concluded that Gilenya should only be used in patients who have a real need for the medicine either because they have failed to respond to at least one other disease modifying therapy or because their disease is severe and getting worse rapidly. In addition, the Committee concluded that all patients should have their heart closely monitored after the first dose. The Committee 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?

A risk management plan has been developed to ensure that Gilenya is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Gilenya, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes 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 intend to 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 also includes information on the tests and monitoring that should be carried out in patients before and after starting or when restarting treatment with Gilenya. The pack will also include information on the registry the company will set up to collect data on babies born to women treated with Gilenya, as well as a patient reminder card with key safety information for patients.

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](http://ema.europa.eu/Find%20medicine/Human%20medicines/European%20Public%20Assessment%20Reports). 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 10-2015.