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Questions and answers

Questions and answers on the ongoing review of Gilenya (fingolimod)

Review follows serious cardiovascular events in patients taking the medicine

The European Medicines Agency is reviewing¹ Gilenya, following cases of death and serious cardiovascular events in patients who had recently started treatment with the medicine. While the review is ongoing, the Agency's Committee for Medicinal Products for Human Use (CHMP) is advising healthcare professionals to intensify monitoring of patients after the first dose.

What is Gilenya?

Gilenya is a disease-modifying medicine which 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 has failed to respond to beta-interferon (another type of medicine used in MS), or is severe and getting worse rapidly. Gilenya is available as capsules.

The active substance in Gilenya, fingolimod, blocks the action of the sphingosine-1-phosphate receptor on T cells (a type of immune cells involved in inflammation). This stops the movement of T cells from the lymph nodes to the brain and spinal cord, thus limiting the damage to nerve cells.

Gilenya has been authorised in the European Union (EU) since March 2011 and has been marketed in 11 EU Member States² as well as Norway. In total more than 30 000 patients have received Gilenya worldwide.

¹ The CHMP assessment is being conducted in the context of a formal review under Article 20 of Regulation (EC) No 726/2004, started at the request of the European Commission on 18 January 2011.

² Austria, Cyprus, Denmark, Finland, France, Germany, Greece, Poland, Portugal, Sweden and the United Kingdom.



What is the problem with Gilenya?

On 12 December 2011, the company that markets Gilenya (Novartis) informed the Agency of the unexplained sudden death of a patient in the United States of America within 24 hours of taking Gilenya for the first time. Six other cases of unexplained death had been reported, three of which were sudden. In addition, other reports included three deaths due to heart attack and one due to disruption of the heart rhythm. Currently it is not clear whether these were caused by Gilenya or not.

At the time of its authorisation, no cases of sudden or unexplained death had been reported in studies with Gilenya. However, it was known that treatment with this medicine caused a transient bradycardia (a decrease in heart rate that is short-lived) and might be associated with atrioventricular block (a type of heart rhythm disorder). Warnings on these effects were included in the medicine's product information and on the need for doctors to observe patients for signs and symptoms of bradycardia for at least six hours after the first dose (or when the last dose had been administered more than two weeks earlier).

What is the current status of discussions at the CHMP?

In light of the currently available information and given the known effects of Gilenya on the heart, the Committee believes that there is a need to gather further information to assess the risk to patients and determine the appropriate action. While the review is ongoing, the CHMP, as a precautionary measure, is giving advice to healthcare professionals and patients.

What is the advice to healthcare professionals?

- Before starting treatment with Gilenya, all patients should have their heart checked by ECG, a test that measures the electrical activity of the heart.
- After receiving the first dose of Gilenya, all patients should have their heart function continuously monitored by ECG for six hours.
- All patients should also have their blood pressure and heart rate checked every hour for six hours after the first dose.
- If patients develop any clinically relevant heart problem (such as bradycardia or atrioventricular block), doctors are advised to consider extending the monitoring period until it is resolved.

What is the advice to patients?

- Patients are advised to immediately report to their doctor any symptoms that could suggest they have a heart problem (such as chest pain, weakness or dizziness).
- Patients who have any questions should speak to their doctor or pharmacist.

What will happen next?

These recommendations are issued in order to protect public health while the review is ongoing. The outcome of this review will be made public after it is finalised. The European Medicines Agency will issue further advice as necessary.

The current EU product information for Gilenya can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports.