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Press Office

Press release

European Medicines Agency starts review of Gilenya (fingolimod)

Doctors advised to intensify cardiovascular monitoring after first dose

The European Medicines Agency has begun a review of the benefits and risks of the multiple-sclerosis medicine Gilenya. This follows concerns over the effects of the medicine on the heart after the first dose.

The review was started following reports of heart problems in patients taking Gilenya, as well as the death of one patient in the United States less than 24 hours after the first dose. The exact cause of this patient's death is still unexplained.

Gilenya has been authorised in the European Union since March 2011 for the treatment of relapsing-remitting multiple sclerosis in patients whose disease has failed to respond to a beta-interferon or is severe and getting worse rapidly. It contains the active substance fingolimod. More than 30,000 patients have received Gilenya worldwide.

While the review is ongoing, the Agency's Committee for Medicinal Products for Human Use (CHMP) is advising doctors to increase their level of monitoring of patients after the first dose of the medicine. This includes electrocardiogram (ECG) monitoring before treatment and then continuously for the first six hours after the first dose, and measurement of blood pressure and heart rate every hour. After six hours, any patients with clinically important heart-related effects, such as bradycardia (a slow heart rate) or atrioventricular block (a problem with the conduction of electricity in the heart), should continue to be managed and monitored until their condition has improved.

The risk of bradycardia after the first dose of Gilenya was known when it was authorised. The medicine's product information already includes recommendations to observe patients for signs and symptoms related to this side effect for at least six hours after the first dose.

Gilenya's marketing-authorisation holder, Novartis, has committed to supplying the Committee with the results of its ongoing investigations into the cardiovascular effects of this medicine. The Committee will take this information into account while carrying out its full review of the balance of benefits and risks of the medicine.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

The Committee expects to finalise its review by the time of its plenary meeting in March 2012.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of Gilenya is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004.
3. In addition to the unexplained death in the US, six other unexplained deaths (including three cases of sudden death) after starting treatment with Gilenya have also been reported. Other reports include three deaths due to heart attack and one due to disruption of the heart rhythm. Currently, it is not clear if these were caused by Gilenya or not.
4. All other opinions and documents adopted by the CHMP at its January 2012 plenary meeting will be published on Friday, 20 January 2012 at 12.00 noon UK time on a dedicated web page.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu