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Press Office

Press release

European Medicines Agency gives new advice to better manage risk of adverse effects on the heart with Gilenya

The European Medicines Agency recommends new advice to healthcare professionals to reduce the risk of adverse effects on the heart associated with the use of the multiple sclerosis (MS) treatment Gilenya (fingolimod).

Following a review of the latest evidence of the safety of the medicine, the Agency's Committee for Medicinal Products for Human Use (CHMP) recommends that doctors should not prescribe Gilenya to patients with a history of cardiovascular and cerebrovascular disease or who take heart-rate lowering medication. However, when treatment with Gilenya is considered necessary in these patients, their heart activity should be monitored at least overnight following the first dose of Gilenya and doctors should seek advice from a cardiologist on appropriate monitoring.

The CHMP also recommends that all patients starting treatment with Gilenya should have their heart activity monitored before receiving the first dose of the medicine and continuously for at least six hours after. Monitoring should be extended for at least two hours in patients whose heart rate is lowest six hours after receiving the first dose of Gilenya. In patients who develop clinically significant heart problems such as bradycardia (a slow heart rate) or atrioventricular (AV) block (a problem with the conduction of electricity in the heart) monitoring should continue at least overnight and until the problems have been resolved.

The detailed new recommendations adopted by the CHMP are available in a question-and-answer document.

Gilenya has been authorised in the EU since March 2011 for the treatment of relapsing-remitting MS in patients who have not responded to treatment with beta-interferon or whose disease is severe and getting worse rapidly. It is the first disease-modifying MS treatment available as an oral formulation.

It has been known since the initial authorisation that Gilenya may cause transient bradycardia – a short-lived decrease in heart rate – and may also be associated with heart rhythm disorders related to AV block. Warnings about these risks were included in the product information.

In January 2012 the Agency started a review of the cardiovascular safety of Gilenya following receipt of information related to an unexplained sudden death in a patient within 24 hours of taking Gilenya

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for the first time. At the time, the CHMP gave temporary recommendations, advising doctors to perform ECG monitoring for six hours after taking the first dose, and to consider the need for extended monitoring.

For this review the CHMP assessed all available data on the heart safety of Gilenya, including reports of 15 cases of sudden or unexplained death in patients treated with Gilenya. The Committee noted that most of the deaths and cardiovascular problems had occurred in patients with a history of cardiovascular problems or taking other medicines. However, the data reviewed were not conclusive as to whether Gilenya was the cause of the deaths. The CHMP also noted the maximum effect of Gilenya on decreasing the heart rate occurred within six hours after the first dose in most patients and that this decrease in heart rate can be reversed if necessary by giving atropine or isoprenaline.

Therefore the CHMP is of the opinion that the possible risk of heart problems in patients taking Gilenya could be minimised by further strengthening the existing warnings on the cardiovascular effects of the medicine and ensuring close monitoring of all patients. With these risk-minimisation measures in place, the Committee concludes that the benefits of Gilenya continue to outweigh the risks.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of Gilenya was 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. The CHMP's opinion will be forwarded to the European Commission for adoption of a decision.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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