EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 May 2012
EMA/337406/2012
Press Office

Press release

European Medicines Agency updates patient and prescriber information for Pradaxa

Data confirm positive benefit-risk balance of anticoagulant medicine, but modifications to product information for clearer guidance needed

The European Medicines Agency has recommended updating the product information for the blood thinner Pradaxa, to give clearer guidance to doctors and patients on how to reduce and manage the risk of bleeding associated with the anticoagulant medicine. Bleeding is a well-known complication of all anticoagulant medicines and Pradaxa has therefore been kept under close review by the Agency's Committee for Medicinal Products for Human Use (CHMP) since its initial authorisation.

Pradaxa is an anticoagulant (a medicine that prevents the blood from clotting). It is prescribed to adults who have had hip or knee replacement surgery to prevent venous thromboembolic events and also to patients with non-valvular atrial fibrillation to prevent stroke and systemic embolism.

The Committee's recommendation to update the product information follows the assessment of all available data, including from post-marketing surveillance, on Pradaxa and the risk of serious or fatal bleedings. The Committee found that the frequency of occurrence of fatal bleedings with Pradaxa seen in post-marketing data was significantly lower than what was observed in the clinical trials that supported the authorisation of the medicine, but considered that this issue should nonetheless be kept under close surveillance.

On the basis of the available evidence, the CHMP concluded that the benefits of Pradaxa continue to outweigh its risks and that it remains an important alternative to other blood-thinning agents. However, the advice to doctors and patients should be updated and strengthened to give clearer guidance on the best use of the medicine. This includes more specific guidance on when Pradaxa must not be used as well as advice on managing patients and reversing the anticoagulant effect of Pradaxa if bleeding occurs.

Patients who are taking Pradaxa, or any other blood thinner, should be aware that they are at an increased risk of bleeding. If they fall or injure themselves during treatment, especially if they hit their head, they should seek urgent medical attention.

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The Agency has produced a question-and-answer document for patients and for healthcare professionals that provides more detailed information on the Committee's recommendations.

A European Commission decision on this opinion will be issued in due course.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information about Pradaxa is available on the Agency's website.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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