



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 November 2011  
EMA/CHMP/903767/2011  
Press Office

## Press release

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# European Medicines Agency updates on safety of Pradaxa

The European Medicines Agency is providing an update on the safety of the anticoagulant medicine Pradaxa (dabigatran etexilate).

Pradaxa has been authorised since March 2008 for primary prevention of venous thromboembolic events in adults who have had elective total hip replacement surgery or total knee replacement surgery. Since August 2011, it is also authorised for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation. The efficacy of Pradaxa as demonstrated in clinical trials remains unchanged.

The Agency is aware of recent media interest regarding fatal cases of bleeding in patients treated with Pradaxa. The risk of bleeding with anticoagulant medicines is well-known. For Pradaxa, this has been reflected since its initial marketing authorisation in the approved EU product information, which recommends that doctors check for signs of bleeding and discontinue treatment in patients with severe bleeding. Pradaxa is contraindicated in a number of conditions, including in patients who are bleeding and patients with severe renal impairment, and it should be used with caution and at lower doses in elderly patients and patients with moderate renal impairment (depending on indication and circumstances).

The issue has been kept under close review and in October 2011 the Agency's Committee for Medicinal Products for Human Use (CHMP) recommended further changes to the product information following reports of fatal cases of bleeding coming from Japan and assessment of the latest available worldwide data on the risk of fatal bleeding.

The recommended updated product information includes advice that renal function be assessed in all patients before starting Pradaxa treatment; while on treatment, renal function should be assessed at least once a year in patients over 75 years of age and whenever a decline in renal function is suspected in patients of any age. Doctors are being informed about the CHMP's recommendations in a letter sent by the marketing authorisation holder.



On 6 November 2011 a worldwide total of 256 spontaneous case reports of serious bleeding resulting in death were recorded in the EudraVigilance database in association with the use of dabigatran, the active substance of Pradaxa. 21 out of these 256 cases were reported in the EU.

The number of reports of bleedings in patients treated with Pradaxa has to be seen in the context of the rapidly increasing use of Pradaxa worldwide as a result of approval of a new indication (prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation) in several regions of the world and also the increased awareness about the drug, a factor that is known to lead to higher than usual reporting of side effects.

The CHMP is of the opinion that the recommended changes to the use of Pradaxa adequately manage the risk of bleeding. The Agency will continue to closely monitor this issue and the overall safety profile of Pradaxa. The Committee will look again at all case reports received so far to confirm that the frequency of occurrence of fatal bleedings has not increased and that the recommended product information is appropriate to manage the risk.

Patients who wish to have more information about their Pradaxa treatment should contact their doctor. Patients who are taking Pradaxa must not stop their treatment without consulting their doctor.

### **Notes**

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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](http://www.ema.europa.eu)

### **Contact our press officers**

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