

Renal-assessment update issued for dabigatran

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Ingelheim am Rhein, Germany - Boehringer Ingelheim is cautioning doctors in Europe to evaluate their patients' renal function prior to treatment with **dabigatran etexilate** (Pradaxa) and to continue renal assessment whenever a possible decline in renal function is suspected [1].

The company announced an agreement with the **European Medicines Agency** to send an update to European doctors emphasizing the importance of renal assessment with dabigatran, which is approved in Europe for prevention of stroke or embolism in patients with nonvalvular atrial fibrillation and one or more risk factors, as well as the prevention of venous thromboembolic events in total hip- and knee-replacement surgery. In patients older than 75 or with renal impairment, renal function should be assessed at least annually, and the drug should not be given to patients with creatinine clearance less than 30 mL/min.

In addition to the update, the company will strengthen the summary of product characteristics and the prescriber guides packaged with dabigatran.

On November 2, Reuters quoted a Boehringer spokesperson confirming that 50 people worldwide have died from bleeding linked with dabigatran use—"a reasonable order of magnitude." Data from the US adverse-event reporting system suggest that fatal bleeding deaths due to **warfarin** averaged 71 per year over a 14-year period in the US alone [2].