Generic Name:
Dabigatran etexilate
Trade Name:
Pradaxa
Company:
Boehringer Ingelheim
Notes:

The benefits of dabigatran continue to outweigh its potential risks for patients with nonvalvular atrial fibrillation, FDA said in a safety communication issued today. The agency is currently reviewing postmarketing reports of serious bleeding in patients taking this medication that have been submitted to the Adverse Events Reporting System (AERS) database. Specifically, FDA is analyzing the events to determine whether the reports of bleeding in patients taking dabigatran are occurring more commonly than would be expected, based on original observations from the RE-LY trial.

The agency is working with the manufacturer to analyze postmarketing reports for evidence of inappropriate dosing, use of interacting drugs, or other clinical factors that might lead to a bleeding event. In addition, FDA is also using its Mini-Sentinel active surveillance system to compare new users of dabigatran and warfarin with respect to the likelihood of being hospitalized for bleeding.

FDA recommends that health care professionals continue to use dabigatran in accordance with recommendations in the drug label.

Medication Monitor Categories:
Alerts and Recalls