NHS
County Durham and Darlington

Medicines Management Commissioning

Prescribing Memo

Dabigatran (Pradaxa®)

Date: 25.2.13 **Memo Number: 03/13**

MAIN POINTS:

Dabigatran (Pradaxa®) is now contraindicated in patients with prosthetic heart valves who require anticoagulant treatment.

This updated contraindication applies to all strengths.

The European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) have updated the contraindications of dabigatran (Pradaxa®) EMA decision

The previous caution for use of dabigatran (Pradaxa®) in patients with prosthetic heart valves is strengthened to a contraindication based on the availability of new data from clinical trials.

A phase II study examined dabigatran etexilate and warfarin in a total of 252 patients with recent mechanical heart valve replacement surgery (i.e. within the current hospital stay) and in patients who received a mechanical heart valve replacement more than three months ago. More thromboembolic events (mainly strokes and symptomatic/asymptomatic prosthetic valve thrombosis) and more bleeding events were observed with dabigatran etexilate than with warfarin. In the early post-operative patients, major bleeding manifested predominantly as haemorrhagic pericardial effusions, specifically in patients who started dabigatran etexilate early (i.e. on Day 3) after heart valve replacement surgery.

Affected patients should be referred to the initiating trust for appropriate choice of an antithrombotic agent for the prevention of thromboembolic complications.
The product information text (SPC) has been revised to include this new information
www.medicines.org.uk