PhVWP recommended SPC wording for pamidronic acid and risk of Atrial fibrillation

Agreed by PhVWP September 2008

SPC section 4.8 *(pamidronic acid)*

"When the effects of zoledronic acid (4 mg) and pamidronate (90 mg) were compared in one clinical trial, the number of atrial fibrillation adverse events was higher in the pamidronate group (12/556, 2.2%) than in the zoledronic acid group (3/563, 0.5%). Previously, it has been observed in a clinical trial, investigating patients with postmenopausal osteoporosis, that zoledronic acid treated patients (5 mg) had an increased rate of atrial fibrillation serious adverse events compared to placebo (1.3% compared to 0.6%). The mechanism behind the increased incidence of atrial fibrillation in association with zoledronic acid and pamidronate treatment is unknown."

PL section 4 *(pamidronic acid)*

"Irregular heart rhythm (atrial fibrillation) has been seen in patients receiving pamidronate. It is currently unclear whether pamidronate causes this irregular heart rhythm. You should report to your doctor if you experience irregular heart rhythm during treatment with pamidronate."