

Alendronic acid and the risk of stress fractures of the proximal femoral shaft

Final SPC and PIL wording agreed by the PhVWP in April 2009

*Doc. Ref.: CMDh/PhVWP/004/2009
April 2009*

SPC

Section 4.4 Special warnings and precautions for use

Stress fractures (also known as insufficiency fractures) of the proximal femoral shaft have been reported in patients treated long-term with alendronic acid (time to onset in the majority of cases ranged from 18 months to 10 years). The fractures occurred after minimal or no trauma and some patients experienced thigh pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture. Fractures were often bilateral; therefore the contralateral femur should be examined in bisphosphonate-treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures was also reported. Discontinuation of bisphosphonate therapy in patients with stress fracture is advisable pending evaluation of the patient, based on an individual benefit risk assessment.

Section 4.8 Undesirable effects

Stress fractures of the proximal femoral shaft (see section 4.4).

PIL

Section 4 Possible side effects

Fracture of the thigh bone in patients on long-term treatment with alendronic acid. Thigh pain, weakness or discomfort may be an early indication of a possible fracture of the thigh bone.