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Press Office

Press release

European Medicines Agency concludes class review of bisphosphonates and atypical fractures

Rare atypical fractures of the femur: a class effect of bisphosphonates

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that rare atypical fractures of the femur are a class effect of bisphosphonates.

The CHMP confirmed that the benefits of bisphosphonates in the treatment and prevention of bone disorders continue to outweigh their risks, but that a warning of the risk of atypical femoral fractures should be added to the prescribing information for all bisphosphonate-containing medicines in the European Union. Such a warning had already been included in the product information for alendronate-containing medicines across Europe, following a review by the CHMP's Pharmacovigilance Working Party in 2008. It will now be extended to the whole bisphosphonate class.

Prescribers of bisphosphonate-containing medicines should be aware that atypical fractures of the femur may occur rarely. If an atypical fracture is suspected in one leg, then the other leg should also be examined. Doctors who are prescribing these medicines for osteoporosis should regularly review the need for continued treatment, especially after five or more years of use.

Patients who are taking bisphosphonate-containing medicines need to be aware of the risk of this unusual fracture of the femur. They should contact their doctor if they have any pain, weakness or discomfort in the thigh, hip or groin, as this may be an indication of a possible fracture.

The marketing authorisation holders of bisphosphonate-containing medicines have been asked to closely monitor this issue.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A question-and-answer document is available on the Agency's website.

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3. Bisphosphonates include alendronic acid, clodronic acid, etidronic acid, ibandronic acid, neridronic acid, pamidronic acid, risedronic acid, tiludronic acid and zoledronic acid.

4. The review of centrally authorised bisphosphonates was conducted in the context of a formal review under Article 20 of Regulation (EC) 726/2004, as amended.

5. The current European public assessment reports (EPARs) for the nine centrally authorised medicines containing bisphosphonates concerned by these referrals (Aclasta, Adrovance, Bondenza, Bondronat, Bonviva, Fosavance, Ibandronic acid Teva, Vantavo and Zometa) can be found on the Agency's website.

6. The review of nationally authorised bisphosphonates was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.

7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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