Bisphosphonates (Osteoporosis Drugs): Label Change - Atypical Fractures Update

[13/10/2010]

美國 FDA 說明常用於預防或減緩停經後婦女骨質流失(骨質疏鬆)之雙磷酸鹽類(bisphosphonates)藥品可能會造成股骨非典型骨折之風險，如股骨轉子骨下骨折和股骨股幹骨折(Subtrochanteric and diaphyseal femur fractures)，雖然該等骨折並不常見，所有髖關節以及股骨骨折中，出現機率少於 1%，且是否為該類藥品所引起乃未清楚，但仍有案例報告顯示可能與長期使用該類藥品相關。因此美國 FDA 要求該類藥品訪單加註相關警語以及注意事項。

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AUDIENCE：Patient, Family Practice, Geriatric

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ISSUE:FDA is updating the public regarding information previously communicated describing the risk of atypical fractures of the thigh, known as subtrochanteric and diaphyseal femur fractures, in patients who take bisphosphonates for osteoporosis. This information will be added to the *Warnings and Precautions* section of the labels approved to treat osteoporosis, including Fosamax, Fosamax Plus D, Actonel, Actonel with Calcium, Boniva, Atelvia, and Reclast (and their generic products). A Medication Guide will also be required to be given to patients when they pick up their bisphosphonate prescription.

BACKGROUND: Atypical subtrochanteric femur fractures are fractures in the bone just below the hip joint. Diaphyseal femur fractures occur in the long part of the thigh bone. These fractures are very uncommon and appear to account for less than 1% of all hip and femur fractures overall. Although it is not clear if bisphosphonates are the cause, these unusual femur fractures have been predominantly reported in patients taking bisphosphonates.

RECOMMENDATIONS: Patients should continue to take their medication unless told to stop by their healthcare professional. FDA recommends that healthcare professionals should discontinue potent antiresorptive medications (including bisphosphonates) in patients who have evidence of a femoral shaft fracture. See the FDA Drug Safety Communication below for additional information.