European Medicines Agency

London, 31 October 2008
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Public statement on Forcaltonin

Withdrawal of the marketing authorisation in the European Union

On 1 October 2008, the marketing authorisation holder (MAH) responsible for Forcaltonin, Unigene UK Ltd, notified the European Commission of its decision to voluntarily withdraw the marketing authorisation for Forcaltonin for commercial reasons. The MAH confirmed that this decision is not related to any safety concerns with Forcaltonin.

Forcaltonin (recombinant salmon calcitonin) was indicated for the prevention of acute bone loss due to sudden immobilisation such as in patients with recent osteoporotic fractures, Paget's disease and hypercalcaemia of malignancy.

Alternative treatments containing the same active substance as Forcaltonin (salmon calcitonin) are available throughout the European Union.

On 29 October 2008, the European Commission issued a decision to withdraw the marketing authorisation for Forcaltonin. Pursuant to this decision, the European public assessment report (EPAR) for Forcaltonin will be updated to reflect that the marketing authorisation is no longer valid.

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