

August 2012

**Direct Healthcare Professional Communication on calcitonin associated with malignancy – withdrawal of Miacalcic 200IU nasal spray, solution from the market**

Dear Healthcare Professional,

**Summary**

**The European Medicines Agency has recently completed a review of the benefits and risks of calcitonin concluding that there was evidence from randomised controlled clinical trials of an increased risk of malignancies with the long term use of calcitonin compared with placebo treated patients.**

**Due to the higher incidence of malignancies, the following is concluded:**

- **Calcitonin should no longer be used in the treatment of established post-menopausal osteoporosis, since the risks associated with calcitonin outweigh the benefits in this indication.**

**Patients being treated for osteoporosis with calcitonin (Miacalcic 200IU Nasal Spray, solution) should be switched to alternative treatment during the next scheduled (or routine) appointment.**

**Further information on the safety concern**

The review by the European Medicine Agency's Committee for Medicinal Products for human use (CHMP) considered information on the risk of all types of malignancies from randomised controlled trials in patients with osteoporosis or osteoarthritis receiving calcitonin nasal spray or an unlicensed oral calcitonin formulation.

Patients treated with calcitonin in these trials had a higher incidence of malignancies. The increased rate of malignancies varied between 0.7% in the oral calcitonin trials and 2.4% for the calcitonin nasal spray trials. Taking into account the increased risk of cancer with long-term use, the CHMP concluded that the risks of calcitonin outweighed the benefits for the treatment of established post-menopausal osteoporosis in order to reduce the risk of vertebral fractures.

As a result of these findings, calcitonin nasal spray, which is authorized only for treatment of post-menopausal osteoporosis, will be withdrawn from the market.

The letter is sent in agreement with the Irish Medicines Board.

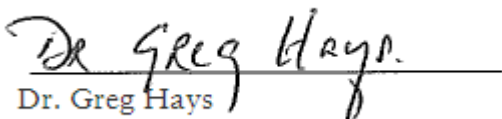
**Reporting suspected adverse reactions:**

Please report any suspected adverse events associated with the use of Miacalcic 200IU Nasal Spray, solution to Novartis Pharmaceuticals Ireland, the Drug Safety and Epidemiology Desk at 01 2080612 or to the Irish Medicines Board

**Communication information:**

If you have any questions or require additional information regarding the use of please contact Dr. Agron Hasani, Novartis Pharmaceuticals Ireland at 01 2601255.

Yours sincerely,

  
Dr. Greg Hays  
Medical Director, Novartis Ireland

**Annex**

Revised wording for Miacalcic 200IU Nasal Spray Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL)