

Bisphosphonates - Small risk of osteonecrosis of the external auditory canal

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has reviewed the available evidence regarding the risk of osteonecrosis of the external auditory canal in patients taking bisphosphonates including data from the published literature and individual case reports. The review concluded that osteonecrosis of the external auditory canal has been reported very rarely with bisphosphonates, mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma.

Osteonecrosis of the external auditory canal is a rare condition affecting the tympanic bone that can occur in the absence of anti-resorptive therapy. The cause is unknown but it has been suggested that it may be a consequence of repeated trauma or due to relatively low vascular supply to the tympanic bone.

The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms including chronic ear infections. Patients should be advised to report any ear pain, discharge from the ear and/or an ear infection during bisphosphonate treatment. The number of reports of osteonecrosis of the external auditory canal reported in association with bisphosphonates is low in comparison with the number of cases reported of bisphosphonate-related osteonecrosis of the jaw (ONJ) which is a well-established side effect of bisphosphonates. However, cases have been reported in both men and women receiving intravenous and oral bisphosphonates for both cancer and osteoporosis indications.

Key message

- A small number of cases of osteonecrosis of the external auditory canal have been reported in patients taking bisphosphonates for both cancer and osteoporosis indications.
- Most cases were associated with long term bisphosphonate therapy and the majority of cases had possible risk factors including steroid use, chemotherapy and/or possible local risk factors such as local infection, or trauma.
- Healthcare professionals should be aware of the risk if patients taking bisphosphonates present with ear symptoms.

**Further details on bisphosphonates authorised in Ireland are available on www.hpra.ie and www.ema.europa.eu*

This section has been supplied by the HPRA for use in MIMS Ireland. However, the HPRA is independent and impartial to any other information contained in this directory.