



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## PRAC recommends further measures to minimise risk of osteonecrosis of the jaw with bisphosphonate medicine

Measures to be considered for other intravenous bisphosphonates and denosumab in upcoming reviews

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a periodic review<sup>1</sup> of one of the bisphosphonate medicines with a known risk of osteonecrosis of the jaw, Aclasta (zoledronic acid). The PRAC recommended a number of measures, including an update to the product information and the introduction of a patient reminder card, to minimise the known risk of osteonecrosis (death of bone tissue) of the jaw.

Aclasta is used to treat diseases that affect the bones, including osteoporosis and Paget's disease. The PRAC concluded that the risk of osteonecrosis of the jaw with this medicine remains very low but recommended measures to further minimise this risk.

The card recommended by the PRAC will remind patients about:

- the benefit of treatment of osteoporosis;
- the risk of osteonecrosis of the jaw during treatment with Aclasta;
- the need to highlight any dental problems to their doctors/nurses before starting treatment;
- the need to ensure good dental hygiene during treatment;
- the need to inform their dentist of treatment with Aclasta and to contact the doctor and dentist if problems with the mouth or teeth occur during treatment.

The product information (i.e. package leaflet and summary of product characteristics) will also include further information on how to minimise this risk.

The PRAC will consider similar revisions to the product information and the introduction of patient reminder cards for other intravenous bisphosphonates, used for osteoporosis or for preventing bone complications of cancers, as well as for denosumab, which is also associated with a risk of osteonecrosis of the jaw. These will be considered during the [upcoming and ongoing periodic reviews](#) for these medicines, which are planned to take place over the course of 2015/2016.

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<sup>1</sup> Periodic safety update single assessment (PSUSA)



The PRAC's recommendations for Aclasta will be sent to EMA's Committee for Medicinal Products for Human Use (CHMP) for the Agency's final opinion.

The text of the updated Aclasta product information and the patient card will be published on EMA's website after the CHMP opinion expected on 26 March 2015.

### **More about the medicine**

Aclasta (zoledronic acid) is a bisphosphonate medicine used to treat osteoporosis (a disease that makes bones fragile) in women who have been through the menopause and in men. It is also used to treat Paget's disease of the bone in adults. This is a disease where the normal process of bone growth is changed.

Aclasta works by reducing the action of the osteoclasts, the cells that break down bone tissue. As a result, Aclasta leads to less bone loss in osteoporosis and less disease activity in Paget's disease.

Aclasta is one of many bisphosphonate medicines with a known small risk of osteonecrosis of the jaw. Denosumab, another medicine use to protect bone, also has this risk.

### **More about the procedure**

The review by the PRAC was a periodic assessment, known as a periodic safety update single assessment (PSUSA), which is a type of routine review carried out for medicines at defined time points after a medicine's authorisation.

During this type of review, the PRAC evaluates any new risks identified in order to determine whether the balance of benefits and risks of a medicine has changed and can make recommendations to better manage or minimise risks.

The PRAC's recommendations will now be sent to EMA's Committee for Medicinal Products for Human Use (CHMP), which will issue the Agency's final opinion. The CHMP opinion will then be sent to the European Commission for a legally binding decision valid throughout the EU.

### **Contact our press officer**

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