

**Denosumab 60mg (Prolia): Introduction of a patient reminder card as a risk minimisation measure for osteonecrosis of the jaw.**

Dear Healthcare Professional,

Amgen Ltd would like to inform you of the introduction of a patient reminder card that is being implemented to increase patients' awareness of the risk of osteonecrosis of the jaw (ONJ) and the necessary precautions to minimise this risk.

**Summary**

- **ONJ is a side effect that occurs rarely in patients treated with Prolia (may affect up to 1 in 1000 people).**
- **A patient reminder card is being introduced to increase patients' awareness of the risk of ONJ and the necessary precautions to minimise this risk.**
- **Patients treated with Prolia should be given this patient reminder card with information on ONJ, as well as the package leaflet. Copies of the patient reminder card are provided with this letter.**

**Further information**

Prolia is indicated for:

- treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women Prolia significantly reduces the risk of vertebral, non-vertebral and hip fractures.
- treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures (see section 5.1). In men with prostate cancer receiving hormone ablation, Prolia significantly reduces the risk of vertebral fractures.

**Why these changes are being introduced**

The European Medicines Agency (EMA) recently undertook a review of the effectiveness of risk minimisation measures regarding the risk of osteonecrosis of the jaw (ONJ) with bisphosphonates and denosumab. This resulted in a recommendation that reinforced safety messages in the product information (Summary of Product Characteristics and Package Leaflet) for these products, as well as a proposal for a patient reminder card, giving details of precautions to take to minimise the risk for ONJ.

Amgen is implementing the changes to the product information recommended by EMA and introducing the patient reminder card. The changes to the product information include revisions to the special warnings and precautions for use. The start of treatment / new treatment course should be delayed in patients with unhealed open soft tissue lesions in the mouth. A dental examination with preventive dentistry and an individual benefit-risk assessment is recommended prior to treatment with Prolia in patients with concomitant risk factors. The management plan of the patients who develop ONJ should be set up in close collaboration between the treating physician and a dentist or oral surgeon with expertise in ONJ.

### **Patient Reminder Card**

The card will remind patients about important safety information that they need to be aware of before and during treatment with denosumab (Prolia) injections for osteoporosis and bone loss including:

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

### **Call for reporting**

Please report any adverse reactions to Cherubino Ltd. via email on [pharmacovigilance@cherubino.com.mt](mailto:pharmacovigilance@cherubino.com.mt) or call on 21343270

### **Contact details**

Should you have any questions or require additional information regarding the use of Prolia please contact Cherubino Ltd via e-mail on [pharmacovigilance@cherubino.com.mt](mailto:pharmacovigilance@cherubino.com.mt) .

Additional copies of the patient reminder card can be requested by e-mail on [pharmacovigilance@cherubino.com.mt](mailto:pharmacovigilance@cherubino.com.mt) or [care@cherubino.com.mt](mailto:care@cherubino.com.mt) or [elaine@cherubino.com.mt](mailto:elaine@cherubino.com.mt)

Sincerely,



Luisa de Piro O'Connell

RP Cherubino LTD

### **Annex**

Patient reminder card regarding osteonecrosis of the jaw

## **Denosumab 60mg (Prolia): Introduction of a patient reminder card as a risk minimisation measure for osteonecrosis of the jaw.**

This reminder card contains important safety information that you need to be aware of before and during treatment with denosumab (Prolia).

Your doctor has recommended that you receive denosumab (Prolia), which is used to treat osteoporosis and bone loss. These diseases involve thinning and weakening of the bones so they may break more easily.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1,000 people) in patients receiving Prolia for osteoporosis. ONJ can also occur after stopping treatment.

It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, there are some precautions you should take.

### **Before starting treatment:**

Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Your doctor may ask you to undergo a dental examination if you:

- were previously treated with another medication being a bisphosphonate
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- are a smoker
- have cancer
- have not had a dental check up for a long time
- have problems with your mouth or teeth

### **While being treated:**

- You should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures you should make sure these fit properly.
- If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor and tell your dentist that you are being treated with Prolia.
- Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of osteonecrosis of the jaw.

Please read the package leaflet that comes with your medicine for further information.

