

### **This reminder card contains important safety information that you need to be aware of before and during treatment with Obodence™▼ (denosumab)**

Your doctor has recommended that you receive Obodence (denosumab), 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 denosumab 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 belonging to a group of medicines called bisphosphonates
- 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 Obodence.
- 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.**

#### **Reporting of side effects**

If you get any side effects talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly to the MHRA via the Yellow Card Scheme website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow Card in the [Google Play Store](#) or [Apple App Store](#), available for free. Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible including the brand name and batch number of the medicine. By reporting side effects, you can help provide more information on the safety of this medicine.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspect adverse reactions.

Side effects can also be reported directly to [bioepis.mi@medinformation.co.uk](mailto:bioepis.mi@medinformation.co.uk)