

## Reporting of side effects

By reporting side effects you can help provide more information on the safety of this medicine. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the ibandronic acid (Bonviva®) package leaflet. You can also report side effects directly (see details below).

Please report side-effects to:  
Diamond Pharma Services Limited  
Suite 2, Ground Floor, Field House, Station Approach,  
Harlow, Essex, CM20 2FB  
United Kingdom

Tel: + 44 (0)1279 406765  
Fax: +44 (0)1279 418964  
email: [atnahspv@diamondpharmaservices.com](mailto:atnahspv@diamondpharmaservices.com)

**Or report to:**  
HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

## Further information

Please read the ibandronic acid (Bonviva®) package leaflet for further information on this medicine. If you have any questions about this medicine, please talk to your doctor, nurse or pharmacist.

## ATNAHS

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## **BONVIVA® (ibandronic acid) PATIENT REMINDER CARD REGARDING OSTEONECROSIS OF THE JAW (ONJ) – FOR INTRAVENOUS INJECTION ONLY**

This patient reminder card contains important safety information that you need to be aware of before and during treatment with ibandronic acid (Bonviva®). Your doctor has recommended that you receive ibandronic acid, which is used to treat post-menopausal women with osteoporosis at increased risk of fracture. This disease involves thinning and weakening of the bones so they may break more easily.

A side effect called osteonecrosis of the jaw (ONJ) (severe bone damage in the jaw) has been reported very rarely in patients receiving ibandronic acid for osteoporosis. ONJ can also occur after stopping treatment. It is important to try and prevent ONJ developing as it is 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, or if you wear dentures.

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, brush your teeth regularly 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 ibandronic acid (Bonviva®)
- 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.

### **Treatment start date and contact details**

Date of first injection/infusion: \_\_\_\_\_

Doctor's name: \_\_\_\_\_

Doctor's contact details: \_\_\_\_\_

Dentist's name: \_\_\_\_\_

Dentist's contact details: \_\_\_\_\_

**Make sure you have a list of all your medicines when you see a health care professional.**

**Please talk to your doctor or nurse or dentist if you have any questions about the information in this card.**