

IBANDRONIC ACID

Concentrate for solution for infusion

PATIENT REMINDER CARD

This reminder card contains important safety information that you need to be aware of before and during treatment with ibandronic acid (2, 4 and 6 mg concentrates for solution for infusion) injections for cancer-related conditions.

Your doctor has recommended that you receive ibandronic acid, which is used in adults and prescribed to you if you have breast cancer that has spread to your bones, or if you have a raised calcium level in your blood due to a tumour. It helps to prevent your bones from breaking or your bones from getting weaker by reducing the amount of calcium that is lost from your bones.

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 cancer-related conditions. 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 a bisphosphonate
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone)
- are a smoker
- 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.

- 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 healthcare professional.

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

Reporting of side effects

You can help by reporting any side effects, you may get. 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 Accord on +44 -0208 901 3370 or safety@lambda-cro.com.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects, you can help provide more information on the safety of Accord Ibandronic acid.

Version 1.03/2017.

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