This reminder card contains important safety information that you need to be aware of before and during treatment with zoledronic acid (4mg/5ml, concentrate for solution for infusion;4mg/100ml, solution for infusion) injections forcancer-related conditions

OSTEONECROSIS OF THE JAW(ONJ)

Your doctor has recommended that you receive zoledronic acid injections to help prevent bone complications (e.g. fractures) caused by bone metastases and/or to reduce the amount of calcium in the blood in adult patients where it is too high due to the presence of a tumour.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported uncommonly in patients receiving zoledronic acid injections for cancer-related conditions. ONJ can also occur after stopping treatment.

In order to reduce the risk of developing ONJ, there are some precautions you should take:

Before starting treatment:

- Ask your doctor to tell you about ONJ before you start treatment
- Check with your doctor whether a dental examination is recommended before you start treatment with zoledronic acid
- Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth

Patients undergoing dental surgery (e.g. tooth extraction(s)), who do not receive routine dental care or have gum disease, are smokers, who get different types of cancer treatments or who were previously treated with a bisphosphonate (used to treat or prevent bone disorders) may have a higher risk of developing ONJ.

While being treated:

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

Read the package leaflet for further information.

Reporting of side effects

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt

Company contact point

Alternatively, suspected adverse reaction may also be reported to the marketing authorisation holders using the details provided below.

Company/ MAH: Central Procurement and Supplies Unit
E-mail: info.CPSU@gov.mt
Tel: (+356) 2540 4000