



30th September 2019

PATIENT REMINDER CARD

This reminder card contains important safety information that you need to be aware of before and during treatment with Zoledronic Acid Seacross 5mg/100ml solution for infusion for cancer-related conditions.

Your doctor has recommended that you receive Zoledronic Acid Seacross 5mg/100ml solution for infusion to help prevent bone complications (e.g. fractures) caused by bone metastases, or bone cancers.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported uncommonly in patients receiving Zoledronic Acid Seacross 5mg/100ml solution for infusion for cancer-related conditions. ONJ can also occur after stopping treatment. In order to reduce the risk of developing osteonecrosis of the jaw, 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 Seacross 5mg/100ml solution for infusion.
- Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

Patients undergoing dental surgery (e.g. tooth extractions), 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 dental check-ups;
- 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 Zoledronic Acid Seacross 5mg/100ml solution for infusion;
- 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.

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. By reporting side effects you can help provide more information on the safety of this medicine.

Read the package leaflet for further information.

This patient reminder card was last revised in 09/2019.

Please discuss any side-effects you get during treatment with your doctor. You can also report side effects directly, reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal

Side effects should also be reported to the local distributor JV Healthcare Ltd (email info@jvpharma.eu Tel: +356 21437551) or directly to Seacross Pharmaceuticals Ltd. Telephone Medical Information: +44 (0)208 731 5273