

- > 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.
- > 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.

If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie Side effects could also be reported to the Seacross Pharma (Europe) Limited preferably via <https://www.seacrosspharma.com>, or by email to drugsafety@seacrosspharma.com

Date of Preparation: November 2024
HPRA approved 03 2025



SEACROSS
Pharma (Europe) Ltd.

PATIENT REMINDER CARD

OSTEONECROSIS OF THE JAW

This reminder card contains important safety information that you need to be aware of before and during treatment with Zoledronic acid Seacross.

PLEASE READ THE PACKAGE LEAFLET THAT COMES WITH YOUR MEDICINE FOR FURTHER INFORMATION.

The package leaflet can be found in the carton (paper copy) or on the HPRA web site (electronic version):
<http://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine>

This material fulfils the conditions of marketing authorization and has been approved by the HPRA in 03 2025.

Your doctor has recommended that you receive Zoledronic acid which is used to treat post-menopausal women and adult men with osteoporosis or osteoporosis caused by treatment with steroids, and Paget's disease of the bone in adults.

These diseases involve 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 Zoledronic 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:



0404065900

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 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.