

Read the package leaflet that comes with your medicine for further information.

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. You can also report side effects directly to Accord Healthcare Ltd. via E-mail: medinfo@accord-healthcare.com; Tel: +44 (0) 1271 385 257, or 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 Zoledronic Acid Accord.

This reminder card contains important safety information that you need to be aware of before and during treatment with Zoledronic Acid Accord for cancer-related conditions

- Your doctor has recommended that you receive Zoledronic Acid Accord to help prevent bone complications (e.g. fractures) caused by bone metastases, or bone cancers and to reduce the amount of calcium in the blood in adult patients where it is too high due to the presence of a tumour. Tumours can accelerate normal bone change in such a way that the release of calcium from bone is increased. This condition is known as tumour induced hypercalcaemia (TIH).

INL5100 10 00000 0 000000

accord

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported uncommonly (1 in 100 people) in patients receiving Zoledronic Acid Accord 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 Accord.
- 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 Accord.
- 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 osteonecrosis of the jaw.