

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

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

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported uncommonly (may affect up to 1 in 100 people) in patients receiving Zoledronic acid Fresenius Kabi injections 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 Fresenius Kabi.
- 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 Fresenius Kabi
- 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.

Read the package leaflet for further information.

Any suspected adverse reactions should be reported immediately to Fresenius Kabi local representative or to the National Pharmacovigilance and Drug Safety Centre.

Fresenius Kabi Local Representative in Saudi Arabia is Alhaya Medical Company

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The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
- SFDA Call center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Online: <http://ade.sfda.gov.sa/>