

This document has been approved by Saudi Food and Drug Authority (SFDA).

Patient Reminder Card

Zodric® (zoledronic acid)

Patient Reminder Card regarding Osteonecrosis of the Jaw

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This reminder card contains important safety information that you need to be aware of before and during treatment with Zodric® (zoledronic acid)

Your doctor has recommended that you receive Zodric® (zoledronic acid), which is used to treat postmenopausal 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) (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.

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:

Before starting treatment:

- Ask your doctor to tell you about ONJ before you start 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, make sure your dentures fit properly and receive routine dental check-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:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects.

To Report any Adverse Drug Reaction or Concerns Please call:

- **Pharmacovigilance Department at MS Pharma:**

- Email: pharmacovigilance@mspharma.com
- Website: www.mspharma.com
- Phone No: + 966112790122 Ext. 6013

- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**

- Email: npc.drug@sFDA.gov.sa
- Call Center: 19999
- Website: <https://ade.sFDA.gov.sa/>
- QR Code:

