

This reminder card contains important safety information that you need to be aware of before and during treatment with zoledronic acid (Zometa) injections for cancer-related conditions.

OSTEONECROSIS OF THE JAW (ONJ)

Your doctor has recommended that you receive zoledronic acid (Zometa) injections.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported uncommonly in patients receiving zoledronic acid (Zometa) 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 (Zometa) and tell your dental provider that you are going to be starting treatment with zoledronic acid
- Tell your doctor/nurse (health care professional) if you have any problems with your mouth or teeth

Patients undergoing dental surgery (eg, tooth extractions) who do not receive routine dental care or patients who 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 checkups
- If you are under dental treatment or will undergo dental surgery (eg, tooth extractions), inform your doctor and tell your dentist that you are being treated with zoledronic acid (Zometa)
- 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.



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You can report any problem or adverse events or request additional copies of the materials through:

Patient Safety Department Novartis Pharma AG - Saudi Arabia.

Toll Free Number: 8001240078

Phone: +966112658100

Fax: +966112658107

Email: adverse.events@novartis.com

Or by online: <http://report.novartis.com/>

Saudi Food and Drug Authority National Pharmacovigilance Center

Unified Contact Center: 19999

Fax: +966112057662

Email: npc.drug@sfd.a.gov.sa

Or by online: <https://ade.sfd.a.gov.sa>

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

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