

Patient reminder card regarding the risk of osteonecrosis of the jaw

PATIENT

This patient reminder card regarding the risk of osteonecrosis of the jaw during the treatment of cancer-related diseases with [injected/infused] medicinal products that contain zoledronic acid was prepared as a part of the authorisation conditions. In the framework of the risk management plan, additional risk-reducing actions that go beyond routine actions were imposed with the authorisation in order to reduce the risk of the occurrence of osteonecrosis of the jaw and to increase the benefit-risk balance of medicinal products that contain zoledronic acid.

This patient reminder card is consequently an obligatory part of the authorisation in order to ensure that the patients know and take into consideration the special safety requirements.

In addition, the patient is to be given the instructions for use for medicinal products that contain zoledronic acid. Please read through these carefully before treatment; they contain further important information.

If you have questions in this regard or are uncertain about anything, please ask your physician or nurse.

Be sure to inform your dentist of the treatment with medicinal products that contain zoledronic acid at your next appointment. You can do this by having your attending physician complete the detachable section of the reminder card for the patient and then giving the section to your dentist.

OSTEONECROSIS IN THE JAW AREA

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

Your physician has recommended that you receive zoledronic acid [injections/infusions] in order to prevent complications in the bones (e.g., bone fractures) due to bone metastases or bone cancer and/or to reduce the calcium level in the blood of adult patients if this level is too high due to a tumour.

An undesirable effect, osteonecrosis of the jaw (bone damage to the jaw), has been uncommonly observed in patients who received zoledronic acid injections for the treatment of cancer-related diseases. Osteonecrosis of the jaw can also occur after the treatment has been stopped.

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Please turn card over

Please detach here



Information for the dentist

DENTIST

Contact data

(To be completed by the attending physician)

Name of the patient

Telephone number

E-Mail

Start of the treatment with zoledronic acid
(Oncological indication)

Name of the physician

Telephone number

E-Mail

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Patient reminder card regarding the risk of osteonecrosis of the jaw

PATIENT

You should take several precautions in order to reduce the risk of developing osteonecrosis of the jaw:

Before starting treatment:

- Ask your doctor to explain osteonecrosis of the jaw before you begin treatment.
- Check with your doctor to see if a dental examination is necessary before you begin treatment with medicinal products that contain zoledronic acid.
- Inform your doctor/nurse (health care professional) if you have any problems with your mouth or teeth.

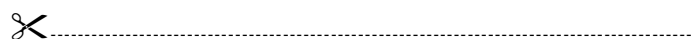
Patients who undergo dental surgery (e.g., tooth extraction), who do not have routine dental examinations, who have gum disease, who are smokers, who receive various types of cancer treatments, or who have already been treated with bisphosphonate (for the treatment and prevention of bone diseases) in the past can have a higher risk of developing osteonecrosis of the jaw.

During treatment:

- You should maintain good oral hygiene. If you have a dental prosthesis (denture), make sure that it fits correctly and have your dentist conduct routine check-ups.
- If you are undergoing dental treatment or are going to undergo dental surgery (e.g., tooth extraction), inform your physician and tell your dentist that you are undergoing treatment with medicinal products that contain zoledronic acid.
- Contact your physician and dentist promptly if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, sores that fail to heal, or a discharge in the mouth or jaw area because these can be indications of osteonecrosis of the jaw.

Read the package leaflet for further information.

Please detach here



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Important information for your dentist

DENTIST

This information for the dentist is an officially supported action intended to ensure that members of the healthcare professions know and take into consideration the special safety requirements associated with the prescription and use of medicinal products that contain zoledronic acid. The patient whose name appears on the front is being treated with zoledronic acid [injections/infusions] in order to prevent complications in the bones (e.g., bone fractures) due to bone metastases or bone cancer or to reduce the level of calcium in the blood of adult patients if a tumour is causing excess calcium in the blood. There have been uncommon (<1 of 100 patients) observations of osteonecrosis of the jaw (ONJ) in patients receiving zoledronic acid [injections/infusions] for the treatment of cancer-related diseases. This can also occur after the treatment has been terminated.

Before starting treatment, patients with risk factors for osteonecrosis of the jaw should undergo a dental examination. Treatment should not be started in patients with unhealed lesions of the soft tissue in the mouth.

Where possible, invasive procedures in the mouth area should be avoided in this patient during the treatment with medicinal products that contain zoledronic acid. Dental treatments can lead to exacerbation in patients who have developed osteonecrosis of the jaw during treatment with a medicinal product that acts on the bones.

If an invasive procedure is necessary, please contact the treating physician to discuss suitable, low-risk treatment options (the physician's contact data is given on the front of this card).

ONJ treatment should be closely coordinated with the physician and a dentist/oral surgeon with expertise regarding ONJ.

Further information can be found in the summary of product characteristics for medicinal products that contain zoledronic acid and on the website of the marketing authorisation holder:

<http://denkpharma.de/indikationsgebiete/amoxi/#collapse7>

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