

Zoledronic Acid Hikma 4 mg/5 ml concentrate for solution for infusion
Zoledronic acid

Patient card for safe use

PATIENT

This patient card was prepared as a mandatory part of the approval of this drug. As an additional risk-minimizing measure, it is intended to ensure that patients are familiar with the specifics of the use of zoledronic acid-containing medicinal products for injection or infusion in the treatment of cancer-related diseases, thereby reducing the potential risk of osteonecrosis of the jaw.

In addition, the patient should be provided with the leaflet for medicinal products containing zoledronic acid. Please read it carefully before treatment, it contains further important information.

If you have any questions or are unsure about anything, ask your doctor or nurse.

Be sure to advise your dentist on treatment with zoledronic acid-containing medicines at the next visit. To do this, you can have the detachable section on the patient's memory card filled in by your attending physician and then hand it over to your dentist.

OSTEONECROSIS IN THE JAW AREA

This patient card contains important safety information that you must observe before and during the treatment of cancer-related diseases with zoledronic acid.

Your doctor has recommended that you receive zoledronic acid injections or infusions to prevent bone complications (such as bone fractures) from bone metastases or bone cancer and/or to reduce the amount of calcium in the blood in adult patients if it is too high due to a tumour.

One side effect, osteonecrosis of the jaw (damage to the bone of the jaw), was occasionally observed in patients who received zoledronic acid for the treatment of cancer-related diseases. Osteonecrosis of the jaw can also occur after the treatment has been completed.

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Important information

DENTIST

for your dentist

Contact details

(To be completed by the attending physician)

Name of the patient.

Telephone number

E-mail

Start treatment with zoledronic acid

(Oncological indication)

Name of the doctor

Telephone number

E-mail

To reduce the risk of developing osteonecrosis of the jaw, you should take some precautions:

Before starting treatment:

- Ask your doctor to inform you about osteonecrosis of the jaw before starting treatment.
- Check with your doctor whether a dental examination is necessary before starting treatment with zoledronic acid-containing medicines.
- Inform your doctor/nurse (health care professional) if you have problems with your mouth or teeth.

Patients undergoing dental surgery (e.g., pulling teeth), who do not have regular dental examinations or have gum disease, who are smokers, who are receiving various types of cancer treatments or who have previously been treated with bisphosphonate (for the treatment and prevention of bone diseases), may have an increased risk of developing osteonecrosis of the jaw.

During treatment:

You should maintain good oral hygiene. Make sure that your denture is properly seated and have regular check-ups by your dentist.

- If you are undergoing dental treatment or are about to undergo dental surgery (e.g., pulling teeth), tell your doctor and tell your dentist that you are being treated with zoledronic acid-containing medicines.
- Contact your doctor and dentist immediately if you have any problems with your mouth or teeth, such as loosening of teeth, pain or swelling, non-healing wounds or leakage of secretions in the mouth or jaw area, as these may be signs of osteonecrosis of the jaw bone.

Read the leaflet for more information.

Reporting of side effects:

If you experience any side effects, talk to your doctor or pharmacist. You can also report side effects using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>, and sent by post or email to the Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 : postlicensing.medicinesauthority@gov.mt. You may also report directly to the MAH by email ckaletta@hikma.com or dl-muc-gs@hikma.com. By reporting side effects, you can help provide more information on the safety of this medicine.

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Important information for your dentist**DENTIST**

This information for the dentist is an officially supported measure to ensure that healthcare professionals are aware of and take into account the special safety requirements associated with the prescription and use of zoledronic acid-containing medicinal products. The patient listed on the front is being treated with zoledronic acid [injections/infusions] to prevent bone complications (e.g. bone fractures) from bone metastases or bone cancer, or to reduce the amount of calcium in the blood of adult patients if too much calcium occurs in the blood due to a tumour. Occasionally (< 1 in 100 treated), osteonecrosis of the jaw (ONJ) has been observed in patients receiving zoledronic acid [injections/infusions] for the treatment of cancer-related diseases. This may also occur after treatment has been terminated.

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

If possible, invasive oral procedures should be avoided in this patient during treatment with zoledronic acid-containing medicinal products. Dental treatment may exacerbate in patients who develop osteonecrosis of the jaw during therapy with a medicine acting on the bone.

If invasive surgery is required, please contact the attending physician and discuss appropriate, low-risk treatment options (see the doctor's contact details on the front of this card).

Treatment of ONJ should be done in close consultation with the doctor and a dentist/oral surgeon with expertise in ONJ.

Further copies of the training material, as well as the technical and practical information, can be downloaded from:

www.medicinesauthority.gov.mt/rmm