

PATIENT REMINDER CARD

Pamifos 3 mg/mL concentrate for solution for infusion Pamidronate Disodium 3 mg/ml Sterile Concentrate

This reminder card contains important safety information that you need to be aware of before and during treatment with pamidronate disodium injections:

Your doctor has recommended that you receive pamidronate disodium injections which are used 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 where it is too high due to the presence of a tumour. It can also be used to treat a bone disorder called Paget's disease of bone.

A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported uncommonly in patients receiving pamidronate disodium injections for cancer-related conditions. ONJ can also occur after stopping treatment.

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.
- Check with your doctor whether a dental examination is recommended before you start treatment with pamidronate disodium.
- 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 pamidronate disodium.
- 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:

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported 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;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt