



MEDICINES RECALL

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level Recall

Date: 7-November-2024

EL (24)A/53

Our Ref: DMRC-33615243

Dear Healthcare Professional,

Ennogen Healthcare Limited

Zoledronic Acid Ennogen 4mg/5ml concentrate for solution for infusion

PL 40739/0233

SNOMED Code 7333011000001103

Batch No	Expiry Date	Pack Size	First Distributed
35000341	Apr-25	1 x 5ml	01 Sep 2023
35000387	Nov-25	1 x 5ml	26 Jan 2024
35000389	Nov-25	1 x 5ml	16 Feb 2024
35000390	Nov-25	1 x 5ml	16 Feb 2024

Active Pharmaceutical Ingredient: zoledronic acid

Brief description of the problem

Ennogen Healthcare Limited has identified that action had not been taken to ensure the Patient Reminder Card (PRC) was distributed alongside the packs of product as part of the approved Additional Risk Minimisation Measures (RMM).

The purpose of the PRC is to alert patients to the risk of osteonecrosis of the jaw (ONJ) and remind them of the precautions to take before and during treatment with zoledronic acid.

This Class 4 Caution in Use notification applies to all batches for PL40739/0233 listed above which were distributed before 17-May-2024.

Ennogen Healthcare Limited has confirmed that all product distributed since 17-May-2024 has been, and shall continue to be, supplied with the PRC.

Advice for healthcare professionals

Ennogen Healthcare Limited confirm that there is sufficient information available to the healthcare professionals administering the medicine via the PIL: [Zoledronic Acid Leaflet 08-07-24 v5.cdr \(medicines.org.uk\)](#), SmPC: [Zoledronic acid Ennogen 4 mg/5 ml concentrate for solution for infusion - Summary of Product Characteristics \(SmPC\) - print friendly - \(emc\) \(medicines.org.uk\)](#), BNF: [Zoledronic acid | Drugs | BNF | NICE](#) to ensure that the relevant cautions whilst taking the medicine and risks associated with ONJ can be discussed during consultation, to make the patient aware of the specific precautions to be taken before and during treatment.

Healthcare professionals can access the electronic versions of the PRC via the following link:

[Zoledronic Acid PA Card 07-12-22 v3.cdr \(medicines.org.uk\)](#)



Medicines & Healthcare products Regulatory Agency

Alternatively healthcare professionals may contact Ennogen Healthcare Limited directly to obtain copies of the PRC for distribution to patients via their clinics by e-mailing MedicalInformation@ennogen.com

Patients being administered the product from the above specified batches should either be provided a link to the online copy of the PRC or given a hard copy.

Advice for patients

Patients should continue to take medicines from these batches as administered by your healthcare professional. This does not affect the quality of the product.

The Patient Reminder Card is an additional measure to ensure ongoing understanding for the patient of risks associated with osteonecrosis of the jaw during treatment, and can be accessed via the following link:

[Zoledronic Acid PA Card 07-12-22 v3.cdr \(medicines.org.uk\)](#)

If you have any concerns about the information provided with your medicine, please speak to your consultant or GP in the first instance.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact MedicalInformation@ennogen.com

For stock control enquiries please telephone +44 (0)1322 629220

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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