Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 11 Aug 2022 EL (22)A/34 Our Ref: MDR 054-08/22

Dear Healthcare Professional,

Sun Pharmaceutical Industries Europe BV

Zoledronic acid SUN 5mg solution for infusion PL 31750/0054

Batch Number	Expiry Date	Pack Size	First Distributed
JKX5541B	11/2022	1x100ml vial	15-Jul-2021
HAC1087A	05/2023	1x100ml vial	15-Oct-2021
HAC3395A	08/2023	1x100ml vial	18-Mar-2022
HAD0156B	01/2024	1x100ml vial	17-May-2022

Active Pharmaceutical Ingredient: zoledronic acid (as monohydrate)

Brief description of the problem
Sun Pharmaceuticals are recalling the above batches of zoledronic acid due to out of specification results observed for Particulate Matter Test during routine stability testing.

This recall is conducted as a precautionary measure as remaining vials may no longer be in line with the licensed product specification with respect to particulate matter.

Advice for healthcare professionals
Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

If patients felt unwell after the administration of the affected batches above, please report this to the Marketing Authorisation Holder and complete a Yellow Card report via the MHRA Yellow Card scheme.

Advice for patients

- Patients are not required to take any action at this time. This product is administered by healthcare professionals only. If you have concerns about zoledronic acid that has been given to you, please contact your healthcare professional.
- The Marketing Authorisation Holder has not received any reports of adverse reactions related to the issue above, however, patients who experience any adverse reactions should seek medical attention. These should also be reported via the MHRA Yellow Card scheme.

Further Information
For more information, medical or supply enquiries, please contact Maciej Rosiak (Qualified Person), +31612091885; maciej.rosiak@sunpharma.com or Gene Kelleher (Head Quality Europe), +353 86 344 1145; gene.kelleher@sunpharma.com

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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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