



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 25 May 2022

EL (22)A/24

Our Ref: MDR 054-02/22

Dear Healthcare Professional,

hameln pharma ltd

Water for Injections BP – 100ml vial

PL 01502 / 0003R

Batch Number	Expiry Date	Pack Size	First Distributed
920503	05/2022	25 x 100 ml	29/11/2019
920506	05/2022	25 x 100 ml	17/12/2019
920508	05/2022	25 x 100 ml	07/01/2020
930503	07/2022	25 x 100 ml	21/01/2020
930504	07/2022	25 x 100 ml	07/02/2020
930505	07/2022	25 x 100 ml	25/02/2020
931501	07/2022	25 x 100 ml	12/03/2020
940501	10/2022	25 x 100 ml	25/03/2020
940502	10/2022	25 x 100 ml	21/04/2020
951504	12/2022	25 x 100 ml	11/05/2020
952501	12/2022	25 x 100 ml	04/06/2020
019501	05/2023	25 x 100 ml	03/07/2020
019502	05/2023	25 x 100 ml	17/07/2020
019503	05/2023	25 x 100 ml	05/08/2020
019504	05/2023	25 x 100 ml	26/08/2020
019505	05/2023	25 x 100 ml	21/10/2020
019506	05/2023	25 x 100 ml	06/11/2020

Active Pharmaceutical Ingredient: Water for Injections

Brief description of the problem

Following further investigations, hameln pharma ltd are recalling the above batches of product additional to the batch recalled on 15 February 2022 (reference [EL\(22\)A/06](#)).

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 the parameters pH and conductivity.

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock of these batches and contact hameln pharma ltd Customer Services on +44 (0)1452 621 661 or customer.services@hameln-pharma.co.uk to arrange credit for any unused vials from these batches or to arrange replacement batches.

Although the Marketing Authorisation Holder have not received any reports of adverse reactions related to the issue above, any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).



Advice to patients

No further action is required by patients as this is a Pharmacy and Wholesaler level recall.

Further Information

For more information or supply queries, please contact or email hameln pharma ltd Customer Services on +44 (0)1452 621 661 or customer.services@hameln-pharma.co.uk

For medical information queries, please contact or email hameln pharma ltd Medicines Information on +44 (0)1452 621 661 or drug.safety@hameln-pharma.co.uk

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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