



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 11 October 2022

EL (22)A/42

Our Ref: MDR 261-05/21

Dear Healthcare Professional,

hameln pharma ltd

**Amiodarone Hydrochloride 50 mg/ml Concentrate for
Solution for Injection/Infusion**

PL 25215/0026

Batch Number	Expiry Date	Pack Size	First Distributed
210505	03/2024	10 x 3 ml	04/08/2022

Active Pharmaceutical Ingredients: amiodarone hydrochloride

Brief description of the problem

hameln pharma ltd is initiating a recall of batch 210505 of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion as a precautionary measure. This is due to an increased presence of visible crystalline particles within the solution, identified during ongoing re-inspection of retained samples.

Advice for healthcare professionals

Please quarantine any remaining stock of this batch 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 ampoules from this batch. Replacement batches of Amiodarone Hydrochloride 50 mg/ml Concentrate for Solution for Injection/Infusion are not available from hameln pharma ltd.

The potential for amiodarone solutions for injection/infusion to crystallise and the associated potential for amiodarone-induced phlebitis are known and have been discussed in a [Direct Healthcare Professional Communication \(DHPC\)](#) previously published on the 24th August 2021.

For all remaining batches Healthcare professionals are advised to visually inspect ampoules of amiodarone for clarity, particulate matter, discolouration and the integrity of the container; Only use the solution if it is clear, free from particles and the container is undamaged and intact.

Advice for patients

Patients are not required to take any action at this time. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.



Medicines & Healthcare products Regulatory Agency

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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