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**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

19 July 2022

Dear Healthcare Professional,

**DRUG ALERT CLASS 2 – 31 2022 – CLASS 2 MEDICINES RECALL – ACTION WITHIN 48 HOURS – HAMELN PHARMA LTD – AMIODARONE HYDROCHLORIDE 50MG/ML CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION**

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

**IRENE FAZAKERLEY**  
**Medicines Policy Team**



# M E D I C I N E S R E C A L L

## CLASS 2 MEDICINES RECALL

**Action Within 48 Hours**  
**Pharmacy/Wholesaler Level Recall**

Date: 19 July 2022

EL (22)A/31

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
207506	02/2024	10 x 3 ml	14/04/2022

Active Pharmaceutical Ingredients: amiodarone hydrochloride

### **Brief description of the problem**

hameln pharma ltd is initiating a recall of batch 207506 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](mailto: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 (product code: AMIOD) are 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](mailto: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](mailto: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

**Defective Medicines Report Centre**  
**10 South Colonnade**  
**Canary Wharf**  
**London**  
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