

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

hameln pharma ltd

PL 25215/0026

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

| 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 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.

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

19th July 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>