



Department of
Health

An Roinn Sláinte

Máinnistrie O Poustie

www.health-ni.gov.uk

For Action: Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

For Information: Assistant Director Integrated Care, Head of Pharmacy
and Medicines Management, HSC Board & BSO

From: Chief Pharmaceutical Officer
Mrs Cathy Harrison
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Our Ref: PHC-22-2021
Date: 3 September 2021

URGENT EARLY MEDICINES SAFETY COMMUNICATION

Dear Healthcare Professional

Zentiva Pharma UK Limited

Gentamicin Intrathecal 5mg/ml Solution for Injection

Batch Number	Expiry Date	Pack Size
224500A	31 Jan 2024	5mg/ml

The Medicines & Healthcare products Regulatory Agency (MHRA) have been informed by Zentiva Pharma UK Limited that Gentamicin Intrathecal 5mg/ml Solution for Injection, batch 224500A, contains lead (Pb) at a level that is potentially above the permitted exposure limits.

The MHRA is working with Zentiva Pharma UK Limited on the investigation into the occurrence of this issue. Whilst the investigation is ongoing, this product should be quarantined as a precaution. Further updates will be provided as the investigation progresses. In the interim period, we ask that healthcare professionals carry out the actions below:

Actions required:

- Healthcare professionals are advised to quarantine this batch with immediate effect.
- No further doses should be administered to patients until further notice.
- Where this product is kept at ward level, this should be returned to the Pharmacy Department as soon as possible.
- Heads of Pharmacy and Medicines Management, or suitable deputies, are requested to inform the Defective Medicines Report Centre (dmrc@mhra.gov.uk) and the Department of Health (pharmacy@health-ni.gov.uk) of the quantities of this

batch that have been returned to, and quarantined by the Pharmacy Department by close of business on Friday 03 September 2021.

- Please inform MHRA DMRC and the Department of Health if any patient has been administered a dose from this batch.

Recipients of this safety communication 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.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Cathy Harrison', written in a cursive style.

Mrs Cathy Harrison
Chief Pharmaceutical Officer