Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Hospital Pharmacy, Ward and Operating Theatre Level

Date: 17 October 2017 EL (17) A/10 Our Ref: MDR 38-02/17

Dear Healthcare Professional

Marketing Authorisation Holder	Product	PL Number
B Braun Melsungen AG	Gentamicin 1mg/ml Solution for Infusion	03551/0116
B Braun Melsungen AG	Gentamicin 3mg/ml Solution for Infusion	03551/0117
Sanofi	Cidomycin (Gentamicin) 80mg/2ml Solution for Injection	04425/0672
Hospira UK Limited	Gentamicin40mg/ml Injection	04515/0037
Zentiva	Gentamicin Intrathecal 5mg/ml Solution for Injection	17780/0506
Zentiva	Gentamicin Paediatric 20mg/2ml Solution for Injection	17780/0507
Amdipharm UK Limited	Gentamicin 40mg/ml Solution for Injection	20072/0056
Wockhardt UK Limited	Gentamicin 10mg/ml Solution for Injection or Infusion	29831/0659
Wockhardt UK Limited	Gentamicin 40mg/ml Solution for Injection or Infusion	29831/0660

The MHRA has recently been made aware that some batches of Gentamicin Sulphate Active Pharmaceutical Ingredient (API) used to manufacture the above finished products may contain higher than expected levels of histamine, which is a residual from the manufacturing process. Batches of API produced between the second half of 2014 and June 2017 are potentially affected. A recall is not considered appropriate at this stage.

Healthcare Professionals are advised to be cautious when using the above products. In particular, caution should be taken when using gentamicin concomitantly with drugs known to cause histamine release (for example opioids and muscle relaxants).

Patients should be monitored closely for potential adverse reactions associated with increased levels of histamine, which may cause anaphylactoid (for example flushing, itching, urticaria and shortness of breath) or hypotensive reactions and increased heart rate. In particular, heart rate and blood pressure should be monitored throughout administration. Paediatric patients and patients with severe renal impairment may be more susceptible to the effects of exogenous histamine, therefore these patients should be monitored more closely. Any suspected ADRs observed should be reported to the relevant Marketing Authorisation Holder and to the MHRA on a Yellow Card

Date: 17 October 2017 EL (17) A/10 Our Ref: MDR 38-02/17

Contact Information

B. Braun Melsungen AG	Mrs Catherine Clulow, Team Leader Quality Complaints Tel 0114 2259155
Sanofi and Zentiva	Sanofi Medical Information Department Tel 0845 3727101; email UK-Medicalinformation@sanofi.com
Hospira UK Limited	Pfizer Medical Information Tel 01304 616161; email Medical.Information@pfizer.com
Amdipharm UK Limited	Stock: Concordia Customer Care Tel 08708 877025; email customercare@concordiarx.com Medical Information: Tel 08700 703033; email medicalinformation@concordiarx.com
Wockhardt UK Limited	Medical Information. Tel 01978 661261; email drug.safety@wockhardt.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant hospital pharmacists, hospital clinicians, nurses and operating theatre staff by copy of this letter. In addition, the relevant Healthcare Professionals should be informed where the product is being used in a domiciliary setting.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor
Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574