Northern Devon Healthcare NHS Trust

Number 41
October 2017

Patient Safety DRUG ALERT

Gentamicin injection : Caution in Use

The Trust has been made aware that some batches of Gentamicin Sulphate may contain higher than expected levels of histamine as a result of the manufacturing process. Batches produced between the second half of 2014 and June 2017 are potentially affected:

Marketing Authorisation Holder	Product	Product License (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

**** Brands highlighted in bold are the brands stocked by Northern Devon Healthcare Trust***

******* a product recall has not been considered appropriate at this stage *******

FOR ACTION:

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, such as 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 or via the website https://yellowcard.mhra.gov.uk/

Please ensure all relevant practitioners (pharmacists, hospital clinicians, nurses and operating theatre staff) are made aware of this information and that it is displayed where staff are able to access and read it.

Practitioners working in a community or domiciliary setting should also be aware of this safety alert, due to the possibility of use of the product in these settings.