

Safeguarding public health  
Defective Medicines Report Centre  
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MHRA

## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use  
Distribute to Hospital Pharmacy Level

Date: 06 March 2013

EL (13)A/09

Our Ref: MDR 03-03/13

Dear Healthcare Professional,

### Hospira UK Limited

#### Cytarabine Injection 100mg/ml (1g/10ml)

PL 04515/0057

| Batch Number | Expiry Date | Pack Size | First Distributed |
|--------------|-------------|-----------|-------------------|
| Z031966AA    | March 2014  | 1 x 10 ml | 06 December 2012  |

Hospira UK Limited has identified the potential for crystallisation in the above batch of Cytarabine Injection 100mg/ml (1g/10ml). The crystals have been determined to be the active ingredient Cytarabine. Hospira UK Limited have identified the most probable cause for crystallisation is from particles of dried Cytarabine introduced during the filling process, which acted as a seed for crystal formation.

The company has informed the MHRA that no adverse events have been reported in connection with this crystallisation issue.

Healthcare Professionals are asked to visually inspect vials for particulate matter prior to use. If crystals are found the product should not be used.

To obtain replacement stock please contact Hospira UK Limited Customer Services on [custserv@hospira.com](mailto:custserv@hospira.com)

For medical information enquiries please contact Hospira UK Limited Medical Information on +44 1926 834400, or e-mail [medinfouk@hospira.com](mailto:medinfouk@hospira.com)

Contd/...

#### MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units  
Chief Pharmacists: England, Scotland, Wales, Northern Ireland  
Prison Health Policy Unit (DH)  
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar  
Special Hospitals  
Healthcare Commission for distribution to Independent Health Care Establishments  
Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)  
151 Buckingham Palace Road London SW1W 9SZ UK  
T 020 3080 6000 [www.mhra.gov.uk](http://www.mhra.gov.uk)

An executive agency of the Department of Health



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Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary care trusts are asked to forward this to relevant clinics and to general practitioners and community pharmacists for information.

Yours faithfully

Adam Burgess

MHRA DMRC Manager